Medicines and Healthcare Products Regulatory Agency

Future regulation of medical devices in the UK

A response by the Association of Personal Injury Lawyers

November 2021

Response on Medical Devices Regulation

Introduction

APIL welcomes the opportunity to respond to the Medical and Healthcare products Regulatory Agency (MHRA) review of medical devices regulation. We agree with proposals to broaden the definition of implantable devices, that manufacturers should hold adequate liability insurance, and in cases where the manufacturer is based outside of the UK, a "UK responsible person" should be liable on the same basis as the manufacturer. These proposals are far from a panacea however, and this consultation is a missed opportunity to properly review and reform the regulatory regime for medical devices in the UK.

General comments

We note that the ministerial foreword to the consultation makes reference to the failures in patient safety that were the catalyst for the Cumberlege report. It is disappointing that the body of the consultation only makes passing references to patient safety. The paper is a missed opportunity for a full review and overhaul of the current regulatory system to ensure that it is robust enough to prevent any of the issues that lead to the Cumberlege report from occurring again. As the review pointed out[1], post-Brexit, there is an opportunity to bring about much needed cultural and legislative reform for the MHRA, and for the agency to become more public facing. The report suggested that the MHRA needs to work for patients and with them, the views of patients need to be systematically listened to and their experiences used to inform licensing and regulatory decisions. There are no proposals in the consultation addressing the way that the MHRA operates, and there is very little focus on proposals that would actually reduce harm to patients, such as listening to patients' experiences, the creation of registries, holding manufacturers to a higher standard, and more checks on products.

Instead, the main aim of the consultation appears to be the introduction of a separate regulatory framework for medical devices in the UK now that we are no longer a member of the European Union. There is no examination of the current effectiveness of the MHRA or how improvements could be made to make the regulatory system stronger to protect patients.

There is also no consideration of the problems that are likely to be posed as a consequence of the separate regulatory framework. Requiring manufacturers to comply with a separate set of regulations to bring products to the UK market will increase costs for those manufacturers. Manufacturers may decide not to make a new product available in Great Britain (Northern Ireland will remain within the existing European regime), and instead only comply with the European regime, in order to keep costs down. A separate regulatory regime for medical devices in Great Britain is likely to reduce patients' access to new

[1] Paragraph 1.41 First Do No Harm – The Report of the IMMDS Review

treatments and devices, reducing patient choice and potentially their access to safer products. That Great Britain is an unattractive market for new products will be exacerbated by the current uncertainty around when the new regulatory regime will be introduced – manufacturers will be put off investing their time and resources into compliance with UK certification if they do not know if and when the certification framework will be introduced.

The consultation does not address the additional work that the MHRA will be required to carry out in approving new products to market as well as re-approving those that currently hold the CE mark. Resources are being cut from the MHRA at present, and we are concerned about the impact that this will have on the agency's ability to effectively regulate devices on the market.

We are also concerned that there do not appear to be any proposals within the consultation to share information with other regulators. It is vital that regulators share information so that if a regulator in another country suspects that a device is defective, the UK regulator can be made aware of this and act accordingly.

There is praise in the minister's foreword about the relationship between manufacturing, innovation and regulation. While it is important not to stifle innovation, we believe that at present the balance is tipped too far the other way, with a light touch approach to regulation which results in fewer checks ultimately being a threat to patient safety. The UK's regulatory regime must be more robust, and must be more effective to protect patients. Instead, to maintain an image of being at the forefront of innovation, the UK risks becoming a "bargain basement" market, whereby manufacturers only have to comply with bare minimum standards in order to sell their products in the UK. As the ministerial foreword states – when it comes to the safety of medical devices, we can, and must, do better.

Consultation questions

We have responded to questions within our remit only.

Products without a medical purpose

Q2.1 Do you think the scope of the UK medical devices regulations should be broadened to include devices without a medical purpose with similar risk profiles to medical devices?

We would agree with proposals that devices inserted for non-medical purposes should be included within the regulations. A contact lens worn for cosmetic purposes poses the same risks as a contact lens worn for medical purposes, and should be manufactured under the same level of scrutiny.

Classification of general medical devices

Q5.1 Do you think the classification rules for general medical devices in the UK medical devices regulations should be amended in any or all of the ways set out in paragraphs 5.8-5.10? ('Yes' / 'No' / 'Don't Know/No Opinion')

We agree that hip implants and surgical mesh should be moved into the highest risk category. We would go further and suggest that any device that is surgically inserted into the body – even those that are temporarily inserted – should be in the highest category of risk. Case law[2] has now recognised that there is a special duty on manufacturers of devices such

[2] Boston Scientific Medizintechnik (Judgment) [2015] EUECJ C-503/13 and C-504/13
In cases regarding defective pacemakers and implantable defibrillators, the European Court of Justice held that where it is found that such products belonging to the same group or forming part of the same production

as pacemakers and implantable defibrillators to meet a particularly high standard in relation to safety, so it would be logical for these to be in the highest risk category. This is due to the vulnerable nature of the patients using these devices, and the greater potential for damage to the patients should something go wrong. When any surgical device is inserted into a person, there is a significant potential for injury, should the device be defective, which we think would warrant all implantable devices being in the highest risk category.

Q7.1 Do you think that the UK medical devices regulations should include a requirement for manufacturers to have measures in place (for example, sufficient financial coverage) for recompensing those impacted by adverse incidents with medical devices on the UK market?

We believe that the UK medical devices regulations should include a requirement for manufacturers to have measures in place for recompensing those impacted by adverse incidents with medical devices on the UK market. Within the EU, Article 10 of the Medical Device Regulation EU2017/745 provides "Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law". We hope that the UK Regulatory regimen would not fall behind the EU in this respect. A simple requirement to hold insurance will not be enough, however, as current experiences demonstrate. Members report that even in some cases where insurance is held by the manufacturer, it has not been possible to pursue a successful claim against them because the policy in question operates on an aggregate basis with a low overall limit of liability. If other claims have in aggregate exceeded the financial limit on the policy, it will not be possible to pursue the current claim where the manufacturer is insolvent or been wound up. In order to protect patients and ensure that they have proper recourse to redress if they are harmed by a defective medical device, a requirement to hold insurance must be accompanied by a requirement within regulations that the limit of indemnity on these claims should be sufficient to cover all likely claims having regard to the types of loss suffered. Insurers should be required to take on the risk of the loss suffered.

In other cases, the manufacturer's insurer has refused to honour the claim because there has been a breach of contract by the insured. In a case relating to defective hip prosthesis, for example, the defendant was said to have insurance but did not seek indemnity as their claim was likely to be rejected for material non-disclosure. We believe that there must be a right for the injured party to proceed directly against the third-party insurer – as is the case in road traffic accident claims, without any right for the insurer to avoid liability on the basis of a breach of contract by their insured. An insurer could otherwise allege late reporting of a potential claim in any circumstance and avoid any liability.

There must also be consideration of how the difficulties arising now that the UK has left the EU and is no longer part of the Lugano convention, will be addressed. If an insurer is based in a foreign jurisdiction, it will not be possible for solicitors based in the UK to bring a claim against a foreign insurer as they were able to pre-Brexit, and the claimant will need to instruct a solicitor in the country that the insurer is based.

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series had a potential defect, it is possible to classify as defective all the products in that group or series without there being any need to show that the product in question is defective. The ECJ found that in light of their function and the particularly vulnerable situation of patients using such devices, the safety requirements for those devices which such patients are entitled to expect are particularly high. The "abnormal potential for damage which those products might cause to the person concerned" was also a factor in the decision.

Responsible persons

Q12.1) Do you think the UK Responsible Person should be explicitly required in the UK medical devices regulations to have an address in the UK at which they are "physically located"?

Yes we do.

Q12.2) Do you think the UK Responsible Person should be legally liable for defective medical devices on the same basis as the manufacturer as outlined in paragraph 12.5?

We welcome the proposal that there should be a UK responsible person who will be legally liable for defective medical devices on the same basis as the manufacturer. As mentioned above, there are now difficulties arising as a result of the UK no longer being part of the Lugano Convention, meaning that it is not possible to pursue a claim against a foreign insurer while based in the UK. Ensuring that foreign manufacturers have nominated a person who is based in the UK who can be pursued on the same basis as the manufacturer, is vital.

The proposal must go further, however. Many cases involving product liability arise many years after the product was first on the market e.g. those relating to asbestos exposure. As such, there can be a considerable delay from when the manufacturer produces the goods and when the loss is sustained. The proposals here only allow for a UK responsible person to be legally liable when the manufacturer supplies the goods, and not when the loss arises in the future. There must be an assurance that the UK responsible person will still be liable in these cases, and it must be possible to trace and take proceedings against this person and to be able to achieve an effective remedy, until all likely claims are extinguished.

Q12.5) What time-period should be specified for the retention of technical documentation relating to implantable devices by the UK Responsible Person?

a. 11-15 years after the last product has been manufactured

b. 16-20 years after the last product has been manufactured

c. for the expected lifetime of the device, after the last product has been manufactured

d. Other (please specify)

The documentation should be maintained for 15 years, or the expected lifetime of the device, after the last product has been manufactured, whichever is longest.

Identification within the supply chain

Q17.1 Do you think the UK medical devices regulations should include the requirements set out in paragraph 17.1 for economic operators to ensure traceability of medical devices?

We agree that economic operators should be required to identify and record: any economic operator who has directly supplied them with a medical device; any economic operator to whom they have directly supplied a medical device; any economic operator who has directly supplied them with a medical device; any public or private sector health institution or healthcare professional to which they have directly supplied a medical device; or any lay person/user/patient/directly supplied with the medical device.

We believe that this requirement should go further, however, and – based on what was recommended in the Cumberlege report - there should be a compulsory requirement for all

medical devices on the market to be placed on a central database, which can feed into specifically created registries for different devices which hold more detailed information on device safety and patient outcomes[3]. This will allow information on the product to be held centrally, and for the products to be properly monitored. Existing registries such as the National Joint Registry have proven to be effective methods of detecting defects, as it is possible to identify what the failure rate of devices are, and what the nature of the defects is, and compare these with different types of devices. Publicly available registries are extremely helpful in empowering patients to make choices, as it allows the public to see failure rates etc depending on the nature of the product – for example the failure rates for different types of hip replacement. However, currently, registries are ad-hoc, niche and have often been created as the result of a catastrophe.

Q26.3. The current timeframe for which manufacturers must retain technical documentation is 15 years for implantable devices, and 5 years for all other medical devices. We are considering whether this is sufficient. An option is for this to be 15 years for implantable devices and 10 years for other medical devices. For how long should the manufacturer be required to keep technical documentation for a medical device they have manufactured?

a. 1-5 years after the last product has been manufactured

b. 6-10 years after the last product has been manufactured

c. 11-15 years after the last product has been manufactured

d. For the expected lifetime of the device, after the last product has been manufactured

e. Other (please specify)

Manufacturers should retain the documentation for the expected longest lifetime of the device, after the last product has been manufactured, or a minimum of 15 years, whichever is longer.

Recording and reporting of adverse events that occur during clinical investigations/performance studies

Q45.1) Do you think sponsors of clinical investigations and performance studies should be required in legislation to fully record and provide information on adverse events, serious adverse events and medical device deficiencies including those set out in points (a) to (d) in paragraph 45.3?

We suggest that this duty should relate to any adverse event, or suspected possible adverse event. Often, there is a period of time when a possible defect in a product comes to light, and/or that a possible adverse event takes place and it is unclear whether it is an adverse event related to the product or not. It would be very important that the regulator should be notified at the point that it is suspected, so that they can have the information as soon as possible, rather than only when the adverse event is confirmed. The regulator would then be

[3] Recommendation 7 in the First Do No Harm report

able to supervise the manufacturer's internal and/or external investigations that take place to ensure these are sufficient.

Reporting of serious incidents and field safety corrective actions

Q49.4. Do you think the manufacturer should be required to report any serious incident in line with the time periods above?

We believe that the manufacturer should report any incident as soon as possible after they become aware of the incident. We also believe that the regulations should be clear that suspected possible incidents should also be reported, not just those where there is a causal link. There is no justification for a delay of 15 days in reporting the incident – in that time, numerous other patients could have been exposed to the dangerous product. 10 or 15 days from the point of awareness of the incident or suspected incident, could expose many people to an unnecessary risk of harm. We would suggest that the requirement for reporting could mirror the requirements in Schedule 1 of the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 in that the responsible person should be required to notify the enforcing authority of the incident by the quickest means practicable without delay and then send a report of the incident in an approved manner to the authority within 10 days of the incident. Given this scenario involves the risk of injury on a large scale the reporting requirements should clearly not be less than for a single workplace incident.

Implantable devices

Q66.1 Do you think there should be any changes to the scope of medical devices regulated as implantable devices?

Yes, we agree with the consultation that temporary devices should be regulated in the same way as permanent devices. Even temporary implanted devices can pose a serious health threat.

We also suggest that there should be a requirement that implantable devices are only administered by specialist centres. The Cumberlege review recommended specialist centres for the treatment of those who have been harmed by mesh, and we suggest this should be expanded to specialist centres for the implantation of such devices in the first instance – this would enable these devices to be tracked and monitored more easily. Such specialist centres could maintain databases of all patients who have had implanted devices so that post-marketing surveillance would be less passive than a system based on yellow card reporting, which is known to under-report the numbers of adverse events.

Any queries about this response should be, in the first instance, directed to:

Alice Taylor
Legal Policy Manager

APIL
3, Alder Court
Rennie Hogg Road
Nottingham
NG2 1RX
Tel: 0115 943 5417
e-mail: alice.taylor@apil.org.uk