Medicines and Healthcare Products Regulatory Agency

Medicines and Medical Devices Act 2021 – Survey

APIL response

September 2025

We welcome the opportunity to respond to the MHRA's call for evidence as part of its review, under the Medicines and Medical Devices Act 2021, of the legislation that governs the development, authorisation, supply, and oversight of medicines and medical devices in the UK. We have not responded to specific questions, but set out below our general views on the regulation of medicines and medical devices in the UK, and the improvements that the MHRA could make to improve public safety. We welcome that this review takes place every five years.

We believe that a full review and overhaul of the current regulatory system is required, to ensure that it is robust enough to prevent any of the issues that led to the Cumberledge report from occurring again. As the Cumberledge review pointed out, 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 a number of ways that the MHRA could change in relation to the way it operates, which would benefit the public and improve public safety. These include patients being able to share their experiences with the Authority, the establishment of medical device registries to improve information sharing, holding manufacturers to a higher standard, and more rigorous and frequent checks on new products entering the market.

Patient safety

A key focus of the MHRA should be patient safety. The framework agreement between the Department of Health and Social Care and MHRA was last updated in April 2024. The four key strategic aims of the MHRA as listed in section 5 of the framework agreement do not explicitly include patient safety. Instead, the Agency is focused towards ensuring rapid access to products, and efficiency in its "business model". We propose that the MHRA's strategic aims are revised so that patient safety is the paramount consideration. We also propose the Agency's strategies should adopt more of a precautionary approach to the avoidance of harms, not sacrificing patient safety for the goal of innovation. There should also be consideration of how the MHRA operates, as highlighted in the First Do No Harm report, to enable it to become more public facing, and the MHRA's work should focus on listening to patient experiences.

We note the recommendation in the Dash review on patient safety, that the Patient Safety Commissioner should be 'hosted' by the MHRA. We question what this would entail, and whether this would impact the Patient Safety Commissioner's independence. It is vital that the Commissioner maintains independence, to fulfil the role effectively.

Information sharing

We believe that there should be a central database for all medical devices, which can feed into specifically created registries for different devices which hold more detailed information on device safety and patient outcomes. Currently, registries are ad-hoc, niche and have often been created as the result of a catastrophe. One example of such an ad-hoc, niche, registry is the Breast and Cosmetic Registry: This Registry has only recently begun to include more comprehensive data from private/independent health providers rendering the historic scope of the data captured limited in coverage. Registries, properly managed and with obligatory data entry requirements for all clinical service providers (private and public), can be effective methods of detecting potential defects, and in empowering patients to make choices, as they allow the public to see and compare failure rates, for example, of a particular product. This is particularly important given the previous Government's decision not to take forward the requirement that economic operators identify and record any lay person/user/patient/directly supplied with the medical device, given concerns about the workability of this requirement in practice. If lay persons/users/patients provided with the device are not identified, it is even more important that there is a central, and publicly accessible, database relating to device safety and patient outcomes, to provide an opportunity for those lay persons/users/patients and medical professionals to identify if there are any issues with the device.

It is also 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. Re-thinking international/EMA links post Brexit should be a priority for the MHRA, and this commitment to international networking, for the benefit of patient safety, should be clearly communicated to the public. 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, and an emphasis on non-disclosure for reasons of "commercial sensitivity", 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, or perhaps more dramatically – an island of "guinea pigs", whereby manufacturers only have to comply with bare minimum standards in order to test, sell and market their products in the UK.

There is also a need for transparency in data regarding manufacturers where there are found to be defects in medical devices. One member reported making a Freedom of Information (FOI) request on how many intraocular lenses had failed, and for a breakdown of manufacturers who had produced the failed lenses. Information was forthcoming on the total number of defective lenses, but no information was shared on who manufactured those lenses, presumably this non-disclosure was justified with reference to "commercial sensitivity", at the potential expense of patient safety. Robust and publicly available registry data would circumvent the need for FOI requests of this nature. Post marketing surveillance of products is required of all manufacturers in any event, the publication of this data adds no additional burden and has the potential to improve patient confidence and patient safety.

Flexibility to new risks and opportunities

The regulatory framework around medical devices must be sufficiently flexible and responsive in its definitions, to adapt to technological advances. We have previously

criticised the law around consumer protection and that it does not currently reflect new technologies such as internet-enabled devices, which are complicating how liability can be attributed when something goes wrong. The 2024 Product Liability Directive broadened the definition of product to include embedded and standalone software, and introduced a presumption of defectiveness in certain circumstances. It is set out in the Directive that "National courts should presume the defectiveness of a product or the causal link between the damage and the defectiveness, or both, where, notwithstanding the defendant's disclosure of information, it would be excessively difficult for the claimant, in particular due to the technical or scientific complexity of the case, to prove the defectiveness or the causal link, or both". Innovative medical devices are expressly mentioned as an example of where there may be technical or scientific complexity to proving defectiveness. The UK regulations covering medical devices should be similarly broadened to cover advances in technology and software.

UK and EU standards

As we have highlighted previously, requiring manufacturers to comply with a separate set of regulations to bring products to the UK market will increase costs for those manufacturers which are likely to be passed on to consumers. Manufacturers may alternatively decide not to make a new product available in Great Britain at all (Northern Ireland will remain within the existing European regime), and instead only comply with the European regime, in order to keep costs down. Therefore, a separate regulatory regime for medical devices in Great Britain is likely to increase costs and reduce patients' access to new treatments and devices, reducing patient choice and potentially their access to safer products.

We are pleased to note, however that in relation to EU regulations, the regulatory status quo will be maintained, and that regulations will continue to apply in Great Britain until such time as they are replaced with updated UK law. We agree that allowing the regulations to expire would cause significant disruption and leave gaps in the current regulatory framework, and would have negative impacts on patient safety.

Review of Regulations 174 and 345 of the Human Medicines Regulations 2012

We suggest that the MHRA undertakes close scrutiny of the operation of Regulations 174 and 345 of the Human Medicines Regulations 2012 in the light of the Covid pandemic in the past 5 years. The MHRA should review and learn any available lessons from the use of these statutory powers during the pandemic.

Regulation 174 provides that medicines can be sold without being authorised, on a temporary basis in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation, which may cause harm to human beings. Consideration should be given to restricting the operation of regulation 174 so that there has to be a confirmed, not just a suspected, spread of pathogenic agents for the regulation to apply. We also suggest that it must be established that the spread would result in a significant level of widespread harm to human beings - not just a possibility of any (perhaps trivial) harm. Currently, there is scope for products to be supplied where it is not proportionate or necessary to take such risks, nor for there to be immunity from civil liability under Regulation 345 - Regulation 345 providing immunity from civil liability where medicines are used without authorisation, in response to the suspected or confirmed spread

of pathogenic agents, toxins, chemical agents or nuclear radiation, which may cause harm to human beings.

We also recommend that any products supplied under Regulation 174 should come with a clear warning to be physically provided in writing to the patient that the product they are about to receive is only authorised on a temporary emergency basis. Patients should be required to sign a consent form to demonstrate their understanding of the basis of the authorisation of the product they are about to receive and the civil immunity which applies to limit the scope of their right to pursue any legal action.

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

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