Responses to the Law Commission's 14th Programme of Law Reform Consultation

The following are the responses to the Law Commission for England and Wales 14th Programme of Law Reform. These were submitted by: Dr Laura Downey, Dr Rachel Dickson, and Professor Muireann Quigley, Birmingham Law School, University of Birmingham on the 31st of July 2021.

For the sake of brevity, we have only included responses to substantive questions asked, omitting questions which were not applicable or administrative. More information about the 14th Programme for Law Reform is available on the Law Commission's website here.

In general terms, what is the problem that requires reform?

The current regulatory framework for medical devices in the United Kingdom (UK) is complex, unwieldy, and needs to be consolidated and simplified. As it stands, the regulatory framework spans several statutory instruments, the principal of which is the Medical Device Regulations 2002. The 2002 Regulations have been amended multiple times. The most recent amendments, at the end of 2020, implemented changes to accommodate the Northern Ireland Protocol and to remove previously inserted provisions mirroring aspects of the EU Regulation on Medical Devices (Regulation (EU) 2017/745) and EU Regulation on In-Vitro Diagnostic Medical Devices (Regulation (EU) 2017/746) (hereafter EU MDR and EU IVDR, respectively).

Many of the recent amendments adopted to facilitate Brexit have not been integrated in one document making navigation of the regulations confusing, labour intensive, and often unclear. Additionally, the Medicines and Medical Devices Act 2021 passed in February this year. This is now the primary legislation governing human medicines, veterinary medicines, and medical devices. In the main, it provides for delegated powers to the Secretary of State to make and amend the existing framework, something that will further add to this complexity. These various pieces of legislation are in urgent need of consolidation and streamlining in order to provide clarity and ease the navigability of the rules for stakeholders, as well as to increase transparency of the regulatory regime for the purposes of scrutiny.

Can you give us an example of what happens in practice?

The current medical device regulatory regime derives from EU law and so implements a similar manner of ex ante regulation to that adopted in the EU. However, successive amendments to the regulations including the most recent statutory instruments which created a dual system of regulation as between Northern Ireland and the rest of the UK (the market of Great Britain) means that the rules for medical devices span multiple legislative instruments. Principally these consist of:

- The Medicines and Medical Devices Act 2021, which is now the primary legislation for medical devices. It mainly provides for delegated powers to amend the existing medical devices regulatory regime.
- The Medical Devices Regulations 2002 (SI/2002/618) (as amended), implementing three different EU Directives (Directive 90/385/EEC, Directive 93/42/EEC, and Directive 98/79/EEC).
- The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, which amend the Medical Devices Regulations 2002 to ensure they continue to have a legal basis post-Brexit. Originally, these Regulations also mirrored key elements contained in the EU MDR and the EU IVDR. However, these were removed by the 2020 Regulations of the same name (see below). The scope of the 2019 Regulations was also limited to England, Wales, and Scotland by the 2020 Regulations.
- The Medical Devices (Amendment etc)(EU Exit) Regulations 2020 implement a dual system of regulation as between Northern Ireland and the rest of the UK by both amending the 2002 Regulations directly and amending the 2019 Regulations of the same name (which in turn amend the 2002 Regulations).

In addition:

- The EU MDR was to be fully implemented by 26 May 2020 and thus would originally have automatically become part of UK-wide law. However, due to the Covid-19 pandemic, the EU delayed this until the 26 May 2021. As a result, it did not automatically become part of UK law, but as per the Northern Ireland Protocol will be in force in Northern Ireland.
- The EU IVDR was never due to apply in UK law except through the mirrored provisions in the 2019 Regulations, which have now been revoked. However, it will apply in Northern Ireland.

For stakeholders wishing to place their devices on the market in the UK, different rules (including administrative and surveillance obligations), in addition to different standards as introduced through the new EU MDR and IVDR, will apply depending on whether the device is being placed on the market in Great Britain or Northern Ireland. The amendments implemented by the 2020 and 2019 Regulations essentially mean that two different versions of the 2002 Regulations now exist. The consequence is that, alongside various guidance documents, stakeholders will have to examine the 2002 Regulations, 2019 Regulations, and 2020 Regulations together (which cover several hundreds of pages of provisions) to determine which rules apply to them.

This demonstrates the complexity of the law as it stands. Yet it is essential that stakeholders can easily and clearly determine their obligations under the law. In order to facilitate this, the law needs to be clear and coherent.

When the complexity of the law threatens coherency and understanding, there is also a danger that it cannot be subjected to appropriate scrutiny. To illustrate, the 2020 Regulations were introduced at the end of 2020 when the new Medicines and Medical

Devices Bill (now Act) was passing through Parliament. The complexity of both the amendments and the existing regulations meant that the changes wrought by the 2020 Regulations went largely unnoticed and unremarked despite being contextually relevant to the debate surrounding the Bill. Further amendments are promised imminently using the powers in the Medicines and Medical Devices Act 2021. This may introduce further complexity to the regulatory regime surround medical devices, something which would impoverish transparency, understanding, and scrutiny of the law in this area.

To which area(s) of the law does the problem relate?

Although this does not represent the totality of the law pertaining to medical devices (which is more extensive than outlined here), the principal pieces of legislation relevant to this submission are:

- Medicines and Medical Devices Act 2021
- Medical Devices Regulation 2002
- Medical Devices Regulation (Amendment etc)(EU Exit) Regulations 2020
- Medical Devices Regulation (Amendment etc)(EU Exit) Regulations 2019
- EU Regulation on Medical Devices (Regulation (EU) 2017/745)
- EU Regulation on In-Vitro Diagnostic Medical Devices (Regulation (EU) 2017/746)

Within the United Kingdom, does the problem occur in any or all of England, Wales, Scotland, or Northern Ireland?

The medical devices regulations are applicable across the UK, although as highlighted different regulations and provisions of the Medical Device Regulations 2002 will apply to Northern Ireland. Those applying in Great Britain implement earlier EU Directives, whilst those applying in Northern Ireland implement the EU MDR (and from May 2022 the EU IVDR). The situation relating to Northern Ireland significantly adds to the complexity of the regulatory framework and is still unfolding as discussions on the application of the Northern Ireland Protocol continue.

The relationships between the Northern Ireland and Great Britain medical devices market need to be clarified and made apparent within the regulations for stakeholders. Transparency and scrutiny of this area is of utmost importance, but this is difficult to undertake given the complexity and extensive nature of law in this area. Consolidation and simplification would remedy this.

What do you think needs to be done to resolve the problem?

The web of provisions across the different regulatory instruments need to be clarified, consolidated, and streamlined in order to represent a transparent and coherent body of law.

This should include considering the range of stakeholders who need to navigate the regulations and their practical needs.

What is the scale of the problem?

Figures from 2019 published by the Office for Life Sciences indicate that the Med Tech sector, that comprises businesses discovering, developing, and marketing medical devices, makes up 40% of the UK life sciences industry. Part of the Government's rationale in bringing forward the Medicines and Medical Devices Act 2021 was to bolster and grow this industry as part of the post-Brexit economy. However, any regulations made under the Act in addition to the pre-existing swathes of legislation, risk adding to the complexity and, thus, impeding growth and innovation in this sector.

What would be the positive impacts of reform?

The benefits of consolidation and simplification of the law in this area would be manifold, including from the categories in the question above (but likely not limited to) economic, improving efficiency/simplicity of the law, and supporting the rule of law.

Consolidating the current medical devices regulatory regime would improve efficiency for stakeholders and those subject to obligations by rendering the law more accessible and coherent. It could also streamline and reduce labour hours (and thus costs) for stakeholders in determining which rules and provisions apply to them. Any cost and labour savings would be particularly welcome for small and medium sized enterprises and start-up companies that typify the medical devices sector. This may be especially relevant to reducing the barrier to start-up companies unfamiliar with medical devices regulation. Arguably, a more straightforward framework would assist innovation and sector expansion in this area.

As touched on in previous answers, consolidation of regulation would increase coherency and clarity, allowing inevitable future amendments to medical device regulation to be properly tracked and subject to proper democratic scrutiny. Currently the complex web of provisions across different legislative instruments mean that the implications and impact of changes might be easily missed by Parliamentarians, stakeholders, and the wider public. Having clear and coherent law is vital to facilitate transparency and the democratic process.

If this area of the law is reformed, can you identify what the costs or other negative impacts of reform might be?

Clearer, transparent, and more accessible law pertaining to medical devices is likely to reduce both administrative and economic costs for stakeholders overall. It might be that a short-term burden is created in having to get to grips with new consolidated/streamlined legislation. However, this would almost certainly be outweighed by the benefits set out previously.

In your view, why is the independent, non-political, Law Commission the appropriate body to undertake this work, as opposed to, for example, a Government department, Parliamentary committee, or a non-Governmental organisation?

The Commission's focus on reform, consolidation, and simplification of the law make it the ideal body to address this issue. Consolidation of the law pertaining to medical devices falls under both the emerging technology and simplification (and arguably also the the legal resilience and leaving the EU) themes set out by the Law Commission with respect to its 14th Programme of law reform.

Importantly, the apolitical, independent nature of the Commission lends advantages over similar exercises that might be conducted by other bodies. Reform of medical devices regulation may be politically contentious given recent developments and amendments, and if it were investigated by a Government Department or Parliamentary Committee it could be perceived as such. There is, in our view, not a non-Governmental organisation with the expertise to carry out either the necessary assessment of the law as it stands or work out the detail of what reform could and should look like.

Have you been in touch with any part of the Government (either central or local) about this problem? What did they say?

Whilst we have not been in contact with Government directly, we raised the issues relating to the complexity of the law in this area in written evidence during the course of Parliamentary debates on the Medicines and Medical Devices Act 2021. We also discussed the need for consolidation of both medicines and medical devices legislation extensively with members of the House of Lords in the run up to the debates, some of whom raised it in the House. As Hansard shows, there was a strong feeling amongst members of the House of Lords that there was a need for reform around medicines and medical devices. This was especially apparent in one of the amendments, which successfully passed at Grand Committee in the Lords. This was a provision committing to consolidating legislation 3 years after Royal Assent.

Although this provision ultimately did not ultimately make it into the Act, there was recognition from members of the Lords (including the Government) that there is a need to clarify and simplify the law relating to medical devices (and medicines). In particular, we understand that during the latter stages of the passage of the Bill, Lord Lansley contacted Sir Nicholas Green on behalf of Lord Patel raising the issue of consolidation and whether this would be the sort of exercise the Commission could undertake. Specifically the enquiry was about medicines, but we understand that Lord Patel had meant the query to address the complexity pertaining to both medicines and medical devices.

Is any other organisation such as the Government or a non-Governmental group currently considering this problem? Have they considered it recently?

To our knowledge, no Government or non-Governmental group is considering this problem. The MHRA is considering what amendments or reforms to the law may be necessary post-

Brexit. However, this does not involve the need for consolidation and streamlining of the regulatory framework.