



Law Society
of Scotland

Call for Evidence

UK Parliament Public Bill Committee

Medicines and Medical Devices Bill

23 April 2020



Introduction

The Law Society of Scotland is the professional body for over 12,000 Scottish solicitors. With our overarching objective of leading legal excellence, we strive to excel and to be a world-class professional body, understanding and serving the needs of our members and the public. We set and uphold standards to ensure the provision of excellent legal services and ensure the public can have confidence in Scotland's solicitor profession.

We have a statutory duty to work in the public interest, a duty which we are strongly committed to achieving through our work to promote a strong, varied and effective solicitor profession working in the interests of the public and protecting and promoting the rule of law. We seek to influence the creation of a fairer and more just society through our active engagement with the Scottish and United Kingdom Governments, Parliaments, wider stakeholders and our membership.

Our Criminal Law Committee welcomes the opportunity to consider and respond to the UK Parliament Public Bill Committee's Call for Evidence on the Medicines and Medical Devices Bill (the Bill). The committee has the following comments to put forward for consideration. We appreciate that the matters to which the Bill relate are not within the legislative competence of the Scottish Parliament and no legislative consent motion is therefore required. There are three aspects which we highlight which include a focus on the purpose of the Bill, the creation of criminal offences and civil sanctions.

Updating existing regulatory frameworks – Part 1 of the Bill

The Bill creates relevant delegated powers to enable the existing regulatory schemes to be updated that include human medicines, veterinary medicines and medical devices. The Bill's targeted powers will allow the UK Government to update the existing regulatory frameworks. This follows the UK's departure from the European Union without the need for primary legislation on the expiry of the Brexit transition period at the end of this year. These delegated powers will build on the existing frameworks and are necessary as the regulation of human medicines (including clinical trials of human medicines), veterinary medicines and medical devices previously fell within the EU competence.¹

We recognise that the Bill provides opportunities for the pharmaceutical industry given that it is a major piece of post-Brexit legislation. However, given the current COVID-19 pandemic emergency, as the scope of the Bill supports the development of medicines and medical devices, scrutiny is required given the implications arising from the potential use of these powers.

Patient safety is paramount. Medicines and medical devices must be both safe and available. How that balance is to be achieved, is left to secondary regulations where further clarification is essential, especially

¹ Relevant statutes include The Human Medicines Regulations 2012, The Medicines for Human Use (Clinical Trials) Regulations 2004, The Veterinary Medicines Regulations 2013 and The Medical Devices Regulations 2002.

given when the Bill was introduced in early February, the full ramifications of this global emergency were unknown and were not appreciated.

The publication of the Independent Medicines and Medical Devices Safety Review under Baroness Cumberlege is significant too though its publication has been delayed to COVID-19.² Though its remit focused on specific medical interventions,³ it was due to consider *“the processes followed by the NHS and its regulators when patients report a problem”* and *“how to make sure communication between the different groups involved is good.”* Recommendations could affect how the healthcare system can improve its response to concerns raised about other medicines and medical devices in the future. This has to be of relevant to the Bill and to scrutiny post COVID-19.

Monitoring by the companies and organisations involved in this business and their operations is required again given the increased public interest and demand at this time with regard to medical vaccine testing and being able to respond to pharmaceutical and equipment demands of the pandemic.

Regarding Scotland, it should be noted that during the UK exit discussions, there was recognition for the need to develop common frameworks to be in place that respected devolution in Scotland, Wales and Northern Ireland. These all comprised highly regulated areas of policy implemented by EU Directives, Regulations and Decisions and were transposed by UK Acts and subordinate legislation, Scottish Acts and Scottish subordinate legislation, as well as administrative, non-statutory arrangements.

The Cabinet Office published in late 2017 a list of 111 points where EU Law intersected with devolved matters which was supplemented by the publication of the UK Government’s Frameworks Analysis: Breakdown of areas of EU law that intersect with devolved competence in Scotland, Wales and Northern Ireland on 9 March 2018.

Some of these areas include those lying within the scope of the Bill that were identified as requiring legislation potentially in relation to:

- Animal health and traceability that refers to EU rules and standards that aim to maintain animal health and allow their movement, including policies covering: prevention of disease (entering UK), control of disease (endemic and exotic), surveillance (for exotic disease) movement of livestock, pet passports and veterinary medicines.
- Medicinal products for human use that relate to medicinal products for human use and, lay down procedures for the marketing authorisation, supervision and pharmacovigilance of these products.

Crucially, these delegated powers permitted by the Bill should only be exercised after consideration has been given to safety of the manufacture, marketing and supply of human medicines and clinical trials and

² <https://www.immdsreview.org.uk/news.html>

³ the hormone pregnancy test Primodos the anti-epileptic drug sodium valproate and surgical mesh

the supply of human medicines in an emergency respecting the assurances provided by the Department of Health that the measures would be subject to "safeguards and limits" aimed at "making the best use of its highly skilled workforce."

Criminal sanctions

The Bill also provides for measures to ensure the enforcement of medical device law and provide scope for UK regulators to restrict the availability of a medical device in order to protect health or safety and to require businesses to disclose information and produce documents in certain circumstances. In relation to the Bill's creation of introduction various offences, we highlight:

Clause 23 of the Bill: This clause creates criminal offences where a person breaches (a) a compliance notice⁴ (b) a suspension notice⁵ (c) a safety notice⁶ or (d) an information notice.⁷

The penalties to be applied differ from England and Wales and Scotland for no particular reason.

In the Bill, these offences are subject to prosecution on summary complaint in Scotland with the maximum sentence restricted to 6 months' imprisonment. The maximum sentence on summary complaint in Scotland would normally be expected to be 12 months imprisonment. This would be in line with the English equivalent sentence outlined in clause 23(2) though we understand that section 154 of the Criminal Justice Act which increases sentencing powers to 12 months is not yet in force. The reality is that the maximum sentence is actually 6 months though the Bill specifies that:

"A person guilty of an offence under subsection (1) is liable (a) on summary conviction in England and Wales, to imprisonment for a term not exceeding 51 weeks, to a fine or to both."

We would suggest that the sentencing provisions are reviewed to ensure consistency across Scotland, England and Wales.

There should also be regard to the Presumption against Short Periods of Imprisonment (Scotland) Order 2019, as that includes a statutory presumption for a court not to pass a sentence of imprisonment for a term of twelve months or less, unless the court considers that no other method of dealing with the person

⁴ the enforcement authority has reasonable grounds to suspect that a person involved in marketing or supplying a medical device is not complying with a medical devices provision. Clause 16 2 the enforcement authority considers that it may be necessary to restrict the availability of a medical device in order to protect health or safety. Clause 17

⁵ the enforcement authority considers that it may be necessary to restrict the availability of a medical device in order to protect health or safety. Clause 17

⁶ The enforcement authority may serve on a person a notice imposing on the person prohibitions or requirements that the enforcement authority considers necessary to restrict the availability of a medical device in order to protect health or safety. Clause 18

⁷ the enforcement authority considers that a person has information which the enforcement authority needs for the purpose of deciding whether to (b) serve or revoke a suspension notice, or (c) serve, vary or revoke a safety notice. Clause 19

was appropriate. It should be noted therefore that custodial sentences for these types of offences would therefore seem unlikely.

Clause 24 of the Bill: This outlines a defence of “due diligence” to offences prosecuted under Clause 23(1) of the Bill. This purports to impose a reverse burden where the legal *burden of proof is (exceptionally) placed on the accused in a criminal case.” These types of burdens are subject to potential challenge in court as being in contravention of Article 6 (2) of the European Convention on Human Rights.

There may be justification for the clause to impose on the defence a legal burden where the defence relates to matters closely tied in with the accused’s own knowledge or state of mind and where the prosecution would face particular problems securing a conviction in the absence of a legal burden.⁸ These presumptions of law (legal burdens) and presumptions of fact (evidential burdens) are permitted provided they are kept within reasonable limits, the rights of the defence are maintained and they take proper account of the importance of what is at stake.⁹ The courts have held where a legal burden is imposed, it must be legitimate and proportionate. Where it is not proportionate, the offending provision should be ‘read down’ to impose only an evidential burden on the accused.

The law is complex in this area and as drafted, there may be challenges in court to the imposition of a legal burden given that the accused is presumed to be innocent with the prosecution required to establish the guilt of the accused beyond reasonable doubt.

Clause 25 of the Bill: This sets out the responsibility of offences committed by bodies corporate which includes Scottish partnerships. It is not clear how these provisions fit in with the Partnership (Prosecutions) (Scotland) Act 2013.¹⁰

Civil Penalties

Schedule I of the Bill sets out the procedure to be followed where the Secretary of State wishes to impose a financial penalty on a person if they are satisfied that the person has committed an offence under Clause 23 or Regulation 60A of the Medical Devices Regulations 2002.

Provisions provide the rights for any person on whom a notice is served to make written representations and objections to the proposed imposition of the monetary penalty. The right to appeal is also included to the First Tier Tribunal which is understandable given that it relates to the imposition of a civil penalty. However, under Schedule 1 Clause 2(8) of the Bill, where the person states that they did not commit an offence, the Tribunal must allow the appeal unless satisfied beyond reasonable doubt that the person committed the offence.

⁸ *Sheldrake v DPP Attorney General's Reference (No. 4 of 2002)* [2003] EWCA Crim 762) 7

⁹ *Salabiaku v France* (1991) 13 EHRR 379)

¹⁰ <http://www.legislation.gov.uk/ukpga/2013/21/contents/enacted>



This seems a slightly awkward importation of criminal standards into a civil tribunal.

For further information, please contact:

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