



Background

The Law Society of Scotland is the professional body for almost 12,000 Scottish solicitors. We seek to influence the creation of a fairer and more just society and are strongly committed to our statutory duty to work in the public interest and to both protect and promote the rule of law. Our Criminal Law Committee has considered The Medicines and Medical Devices Bill (the Bill) which has its second reading scheduled for Monday, 2 March 2020.

Though 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, we highlight three topics as being of interest.

Updating existing regulatory frameworks

One of the Bill's purposes is to introduce delegated powers in human medicines, veterinary medicines and medical devices to allow existing regulatory frameworks to be updated following the UK's departure from the European Union. This is necessary as the regulation of human medicines (including clinical trials of human medicines), veterinary medicines and medical devices previously fell within the EU competence. Several UK Statutes have enacted the EU legislation including 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.

As the UK reaches the end of the transition period, the regulatory schemes for human medicines, clinical trials of human medicines, or veterinary medicines will not be able to be updated through secondary legislation. Accordingly, Parts 1 to 3 of the Bill create the relevant delegated powers to enable aspects of the regulatory regimes for human medicines, clinical trials of human medicines, veterinary medicines and medical devices to be updated.

During the UK exit discussions, there was recognition for the need to develop common frameworks to be in place to recognise devolution in Scotland, Wales and Northern Ireland. These 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 areas that were identified as requiring legislation fall within the scope of this Bill 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.

Criminal Offences

The Bill also seeks to consolidate enforcement provisions for medical devices and to introduce sanctions. Though the Bill includes various offences, we highlight Clause 23 of the Bill that creates criminal offences



where a person breaches (a) a compliance notice¹ (b) a suspension notice² (c) a safety notice³ or (d) an information notice.⁴

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 which would be in line with the English equivalent sentence outlined in clause 23(2):

“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”

With the commencement of the Presumption against Short Periods of Imprisonment (Scotland) Order 2019,⁵ there is a statutory presumption that a court must not 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 was appropriate. Custodial sentences for these offences would therefore seem unlikely, however amendment to the Bill might be appropriate to the level of the Scottish penalty.

Clause 24 of the Bill outlines a defence of “due diligence” to offences that are prosecuted under Clause 23(1) of the Bill. This purports to impose what is referred to as 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 challenge in court as they are potentially 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.⁶ 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.⁷ 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, we recognise that there may well 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 sets out the responsibility of offences committed by bodies corporate which includes Scottish partnerships. It is not clear how this fits in with the Partnership (Prosecutions) (Scotland) Act 2013.⁸

¹ 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

³ 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

⁴ 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

⁵ <http://www.legislation.gov.uk/sdsi/2019/9780111042281/contents>

⁶ *Sheldrake v DPP* Attorney General's Reference (No. 4 of 2002) [2003] EWCA Crim 762

⁷ *Salabiaku v France* (1991) 13 EHRR 379

⁸ <http://www.legislation.gov.uk/ukpga/2013/21/contents/enacted>



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