BIVDA
British In Vitro Diagnostics Association

BIVDA Briefing Note – Medicines and Medical Devices Bill

Context for the Bill

A large proportion of the legal framework for medicines and medical devices in the UK derives from EU Directives and has been implemented into domestic legislation through section 2(2) of the European Communities Act 1972 (ECA). This enables EU Directives to be transposed into UK law through secondary legislation and has been used to create a body of regulations that include the:

Human Medicines Regulations 2012

Medicines for Human Use (Clinical Trials) Regulations 2004

Veterinary Medicines Regulations 2013

Medical Devices Regulations 2002.

At the end of the Transition Period, the European Union (Withdrawal) Act 2018 will have preserved these frameworks as "retained EU Law". The ECA, however, will no longer be available to the UK at this point to amend the regulations. There is no other 'general power' for updating these regulations, except through the introduction of primary legislation.

What does the Bill do?

The Medicines and Medical Devices Bill seeks to address this regulatory gap through introducing regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. Its purpose is to enable the existing regulatory frameworks to be updated at the end of the Transition Period.

The Bill has been drawn to create 'targeted' delegated powers which can only be exercised in relation to a restricted number of matters. The Government stated in the Explanatory Notes to the Bill that it intends to use these powers to keep the existing regulatory frameworks updated, while also consolidating the enforcement regime for medical devices. In addition, the Bill will provide the Secretary of State with the ability to impose civil sanctions – as an alternative to criminal prosecution – for breaches of the medical device regime.

The Government has indicated in the background briefing to the Queen's Speech and in a press release that they intend to use these powers to support the development of medicines and medical devices within the NHS and amend prescribing powers.

Part 1 of the Bill creates a delegated power to amend or supplement human medicines law. The power is restricted to amending four pieces of legislation: the Human Medicines Regulations 2012, the Medicines for Human Use (Clinical Trials) Regulations 2004, the Medicines (Products for Human Use) Regulations 2016 and limited parts of the Medicines Act 1968 (specifically those parts which make provision related to pharmacies). It is then further restricted to amending or updating only those provisions stated on the face of the Bill. These are:

- the manufacture, marketing and supply of human medicines;
- falsified medicines;
- clinical trials;
- the charging of fees in relation human medicines provision;
- creating an offence for failing to comply with human medicine regulations;
- supply of human medicines in an emergency.

Part 2 of the Bill confers a delegated power to amend or supplement the Veterinary Medicines Regulations 2013 and specifically those regulations that relate to:

- the manufacture, marketing, supply and field trials of veterinary medicines;
- the charging of fees in relation human medicines provision;
- creating an offence for failing to comply with veterinary medicine regulations;
- the powers of a Veterinary Medicines Directorate Inspector.

Part 3 of the Bill creates a delegated power to enable the Medical Devices Regulations (MDR) 2002 to be updated, though the Bill stipulates that the Regulations may only be amended in relation to a limited number of areas, namely:

- the manufacture, marketing and supply of medical devices;
- the charging of fees in relation to medical devices (eg to register a device);
- recording information about the safety of devices;
- creating offences of breaching the provisions in the MDR; and
- the supply of medical devices in emergencies.

Part 3 of the Bill also aims to consolidate the enforcement regime for ensuring the safety and quality of medical devices. It provides the Secretary of State with new information sharing powers relating to the safety of a medical device.

Part 4 of the Bill creates a duty to consult before any changes to regulations are made under Clauses 1(1), 8(1) and 12(1) and also provides that the statutory instruments made under these clauses will be subject to the affirmative resolution procedure. Exceptions to the duty to consult, and to the use of the affirmative procedure, are outlined in the paper.

How does the Bill apply to UK nations?

The Bill extends to England, Northern Ireland, Scotland and Wales. Parts 1 and 2 of the Bill (relating to Human Medicines and Veterinary Medicines respectively) are within the legislative competence of the Northern Ireland Assembly and a legislative consent motion has been sought for those parts.

Committee Stage of the Bill

The Committee Stage ran from 8-10 June 2020. Technical amendments were moved by the Government and agreed. No other amendments were made. The Government promised to discuss a UK registry for medical devices, outside of the Committee, following a proposed new clause on this matter.

Medical devices database

The Minister provided further details on the Government's thinking behind a medical devices database:

Currently, medical devices are not subject to the same comprehensive regulatory system of pre-market assessment as for medicines, and the Government recognises that the system could be much more robust

Ahead of the publication of the Cumberlege report, the Government is keen to take action now to close any gaps

While some of the matters dealt with by the registry are already covered by the Health and Social Care Act 2012, which established that the Secretary of State can ask the Health and Social Care

Information Centre (ie NHS Digital) to collect data, there needs to be provisions in place which cover the whole of the UK, and non-NHS private providers, to allow a bigger-picture view

We do have a number of existing registries, ie the National Joint Registry which is a Global Exemplar, but not all high risk devices have a registry

Data is a fundamental driver of change, and the new clause seeks to create the legal backbone for future data collection and construction of a data system to support existing and new registries in the future. Expected benefits of the database are that it would:

- Ensure long term outcomes can be tracked, with a long term aim to intervene earlier through clinical analysis of data to prevent harm before it happens
- Support registries, both present and future, to take action, underpinned by data from all four corners of the UK
- Allow sharing of certain types of information with clinicians, regulators, NHS and other healthcare partners in the longer term
- Improve the data available as part of post-market surveillance, meaning the MHRA is better able to take action early and more effectively

With regards to protecting patient data, Jo Churchill made commitments that regulations will be developed in full consultation with stakeholders. In the shorter term, the Government intends to ensure that data is subject to appropriate safeguards, eg anonymisation by NHS Digital – and that these can and should be in place before the Government is in a position to develop a system of medical registries.

Alex Norris MP, representing the Opposition, agreed with the planned development of a device database, and the new clause was added to the Bill.

The Bill has now completed its Commons stages, and will progress to the House of Lords for consideration – we expect this to take place after the summer, but will keep you updated as and when we know more.