Royal College of Physicians

Briefing

Medicines and Medical Devices Bill 2019-21

This briefing has been produced for the Second Reading of the Medicines and Medical Devices Bill in the House of Lords on Wednesday 2 September 2020.

Summary

The information outlined has been collated by the Royal College of Physicians, the Faculty of Pharmaceutical Medicine and the British Association of Dermatologists. We have outlined several opportunities and challenges which the government ought to consider as the Medicines and Medical Devices Bill progresses through the House of Lords.

The Bill allows the government to update, modify and maintain the regulatory regimes for human medicines, clinical trials of human medicines and medical devices. The Bill would give the government delegated powers to make such changes. Such powers must have regards to the safety and availability of medicines or medical devices as well as the attractiveness of the United Kingdom as a place in which to develop or supply these.

Key calls:

- Commitment from the government to engage early with professions on which medicines will be considered as 'low-risk'. The chosen regulator must also ensure that doctors who have expertise in medicines and the diseases in question are consulted with

- The Bill must include provisions which allow for review of processes for issuing sole manufacturing licenses and consider the use of price control mechanisms in relation to costs of production, to increase access to medicines at fair prices

- We are seeking clarification at the Second Reading that the Bill will include provisions that enable the passage into UK practice of existing EU legislation coming into force in the next few years

- The Bill must include provisions which enable international requirements for the data to be acquired by the UK during the development and supply of medical devices and in vitro diagnostics

- We are calling for the Bill to include provisions for the development of a **rapid provisional 2-year licensing procedure.** This will allow rapid access to the NHS but at the same time protects patient safety.

- In line with recommendations from the Baroness Cumberlege review, this Bill ought to include provisions to ensure the Medicines and Healthcare products Regulatory

Agency (MHRA) engages with patients and their outcomes in relation to adverse event reporting on medical devices as well as in vitro diagnostics.

Human medicines

Prescribing 'low-risk' medicines - regulations made under clause 1(1) and relying on clause 2(1)(i)

This regulation would allow for additional healthcare professionals, such as paramedics and midwives, to be given appropriately restricted prescribing rights or to amend the exemptions to the requirement for a prescription in 'low-risk' circumstances.

The UK already has defined processes in place for non-medical prescribers (e.g. pharmacists) and we believe that **there is no reason to prevent additional healthcare professionals from prescribing provided that their competencies have been assessed in the same way as any other prescriber, and equal safeguards are implemented**. This will be an increasing area for the NHS in future to meet the rising demands of healthcare.

On deciding which 'low-risk' medicines would fall under these new regulations, we argue that the chosen **regulator must consult with doctors who have expertise in medicines and the diseases in question**. Doctors, as the senior decision makers, should also be involved in decisions on the risk status of medicines.

Manufacture, marketing and supply – Clause 2

This section refers to regulations around the manufacture, marketing and supply of medicines in the UK. We are calling for the Bill to consider establishing processes to alter import requirements which enable pharmaceuticals to supply medicines at best value prices. Under subsection (1)(d) **it is important that the Bill considers reviewing the issuing of sole manufacturing licenses and consider the use of price control mechanisms in relation to costs of production, to increase access to medicines at fair prices.**

Clinical trials

The UK framework for clinical trials is based on the EU Clinical Trials Directive and is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004. The EU is repealing and replacing the regulations this directive is based on. It is not due to come into force until after the end of the transition period therefore the new EU regulations would not apply to the UK.

The UK must continue to be able to participate in the Europe-wide clinical trial system. Diverging from EU law on clinical trials could mean that patients miss out on opportunities to take part in medical research, and researchers in the UK find it harder to access EU funds (which are subject to separate negotiations). This would have an adverse impact on patients

with rare diseases who depend on international trials due to low numbers of patients with similar conditions in any one country.

Divergence creates a huge burden for clinicians involved in clinical trials of products that are of international importance. The data may no longer be acceptable to regulatory authorities of other countries, thus rendering the trial void, and the product unable to marketed anywhere else in the world. Divergence creates another layer of bureaucracy and may become a disincentive.

We are seeking commitment from the government that the provisions of this Bill will enable the passage into UK practice of existing EU legislation coming into force in the next few years – particularly the Clinical Trials Regulation (CTR), implementation of which has been delayed pending availability of the EU Clinical Trials portal.

To allow the UK to be a leading global innovator in medicine and medical devices, we are also proposing that the Bill includes provisions for development of a **rapid provisional 2-year licensing procedure.** This will allow rapid access to the NHS but at the same time protects patient safety. Patients receiving these medicines and devices used under this license should be recorded on a centrally held register and outcomes must be monitored at 12-18 months before a formal licence can be issued.

Medical Devices

Power to make regulations about medical devices – Chapter 1, Section 12 (2)

This section states that the *Secretary of State must have regard to safety and availability of medical devices (MD) and make the UK an attractive place to develop and supply MDs.* These objectives can only be met if UK regulations of medical devices, registration procedures and safety data collection are compatible with processes followed across the EU and other major regulatory authorities in areas in which the same devices are used or are under investigation e.g. in the USA.

We are calling for this Bill will include provisions which enable international requirements for the data to be acquired by the UK during the development and supply of medical devices and in vitro diagnostics in order to ensure access relevant safety information and remain an attractive place to develop and supply these.

Disclosure of information - Chapter 3, clause 34-36

These sections concern the disclosure of information and applies in relation to information the Secretary of State holds regarding medical devices.

Whilst this is welcome, such powers could cause unnecessary patient panic which already occurs with medication precautionary alerts. It is therefore essential that **any such public message is clear about the level of risk** and urgency in relation to the statement.

In line with recommendations of the Baroness Cumberlege review, we also call for the Bill to include provisions to ensure the **Medicines and Healthcare products Regulatory Agency (MHRA) engages with patients and their outcomes in relation to adverse event reporting** on medical devices as well as in vitro diagnostics. This is integral to raising awareness of its public protection roles and to ensure patient involvement.

Any new regulation should look to review how the Central Alert Systems work in relation to medical devices so that clinicians can be better prepared for such announcements and able to manage public concerns.

For medicines, the Commission on Human Medicines (CHM) plays a role in the oversight of the risk benefit balance of medicines. **Will the Bill include provisions for the UK to seek a new role for the CHM or another body to** be established that would have the competence to include provision of expert advice on medical devices. The latter would have the merit of being able to focus on a rapidly expanding field of medicine and surgery.

Information system (new clause 16)

The group asks members of the Lords to seek clarification from the minister on plans for the Information System (clause 16) at the Second Reading – would it be a preliminary to a single database on devices?

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Briefing

The RCP has a number of experts that are available for conversations with peers if you have specific questions.

- Professor Andrew Goddard, president, Royal College of Physicians
- Professor Donal O'Donoghue, registrar, Royal College of Physicians
- Dr Sarah Clarke, clinical vice president, Royal College of Physicians
- Professor Yoon Loke, chair of the Joint Speciality Committee for Clinical Pharmacology & Therapeutics, Royal College of Physicians
- Professor Tim Higenbottam, president, Faculty of Pharmaceutical Medicine
- Professor Alan Boyd, past president, Faculty of Pharmaceutical Medicine
- Dr Bryan McDonald, chair of the specials working group at the British Association of Dermatologists
- Dr Deidre Buckley, British Association of Dermatologists
- Dr Wajid Hussain, clinical director for digital health, Royal College of Physicians

Please contact Nikita Vaghjiani, public affairs adviser (RCP), should you wish to get in touch with any of the experts.