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 Commons on Monday 2 March 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. Together we have highlighted several opportunities and challenges which the government ought to consider as this Bill progresses to strengthen regulations on medicines, medical devices and clinical trials in the UK.

The Bill gives power to the Secretary of State to amend existing UK law and adopt additional EU regulations into UK practice resulting from UKs' exit from the EU. Such powers should 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

- The Bill presents an opportunity to streamline access to treatments for patients with chronic conditions such as rare cancers, is welcome. However, it is crucial that strong safeguards regarding quality and safety of such treatments are established. We understand that the European Union Tissue and Cells Directive (EUTCD) is currently being reviewed but would like to seek reassurance from the Government that they will ensure that the UK continues to align UK regulations after the transition period with this directive.

- Granting additional healthcare professionals restricted prescribing rights for 'low-risk' medicines is welcome and can help address the pressures facing the healthcare system. It is crucial that doctors are involved with the decision-making process and closely consulted with on what medicines qualify as 'low-risk'.

- To ensure that the UK remains as one of the best places in the world for science and innovation, the government must commit to aligning guidelines for clinical trials with existing EU legislation.

- It is vital that the practical considerations relating to the powers given to the Secretary of State in this act regarding medical devices are advanced in partnership with clinicians. It would also be timely for DHSC to review how the CAS alerts system works in relation to medical devices.

- To help rapidly expand the field of medicine and surgery, the Bill should 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 Bill should also clarify the role of the MHRA in the qualification of the efficacy and safety of medical devices and in vitro diagnostics. This includes the role they may play in constructing and maintaining a register of products approved for use.

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. We would also encourage the Secretary of State to confirm his plans for a consultation on the future prescribing rights of Physician Associates.

On deciding which 'low-risk' medicines would fall under these new regulations, we argue that the chosen **regulator consults 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. The group calls 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 must continue 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.

The provisions of the Bill enable the Secretary of State to continue to align UK law with EU regulations. **Will the government clarify whether 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. For Medical Devices (MD) and invitro diagnostics (IVD) regulations which come into force respectively in May 2020 (MD) and 2022 (IVD). These directives were passed at a time when the UK was a full member of the EU and contributed to the provisions of the relevant regulations.

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 would like to seek clarification from the government, that 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.

Supply of medical devices - Chapter 1, Section 13 (c)

This section relates to the manufacture, marketing and supply of medical devices. As medical devices may be imported into the UK from many countries it would be **helpful to seek clarification from the government** on how countries or notified bodies might be considered competent to make such an assessment on behalf of the UK.

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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.

The group argues that 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.

Any new regulation should look to review how the CAS alerts system works in relation to medical devices so that clinicians can be better prepared for such announcements better able to manage public concerns. Separately, there is a need to clarify whether these sections enable the Secretary of State to provide for emergency availability of novel diagnostics/therapeutics to protect the public from a risk of serious harm to health, as well as disapply medicines and devices.

The government must clarify the role of the MHRA in the qualification of the efficacy and safety of medical devices and in vitro diagnostics. This includes their role in **constructing and maintaining a register of devices approved for use**. This could be similar to the Summary of the medicinal Product Characteristics (SmPC) which is available for all Market Authorised medicines and is assessible to patients and prescribers. Such an accessible database would provide the means for the MHRA to ensure regular surveillance of CE marked products from all the notified bodies.

The 'Scan4Safety' project introduced in 2016 is an excellent example of how care can be standardised across the entire supply chain. It has helped eliminate avoidable harm in hospitals, including errors such as patients being administered the wrong drugs and surgery being performed on the wrong part of the body.

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.