Medicine and Medical Devices Bill 2020

Second Reading – House of Lords, Wed 2nd September

Briefing for Policymakers from the Urology Trade Association

An estimated 6 million people in the UK (9,000 people on average in each parliamentary constituency) are affected by urinary incontinence and many rely on urology appliances every day. High quality urology appliances allow users to manage their conditions, maintaining their quality of life, affording dignity both at work and home, allowing them independence and avoid repeated medical consultations.

The Medicine and Medical Devices Bill contains a number of measures to ensure that the NHS and patients have faster access to innovative medicines/medical devices. The legislation includes plans to relax rules to allow more NHS staff other than doctors to prescribe drugs to patients, and will aim to give midwives, physiotherapists, paramedics and other staff the power to prescribe what the Department of Health and Social Care described as "low risk medicines" to reduce unnecessary GP appointments. Part 3 of the Bill is on Medical Devices and will give the Government the power to bring forward regulations in the future to amend or supplement the existing Medical Devices Regulations 2002.

This briefing document contains a number of key concerns that the Urology Trade Association has about the Bill, primarily regarding the protection of patient and clinical choice.

General points on governance

The UTA is aware of the concerns expressed by the Lords committees on Delegated Powers and Regulatory Reform (DPRRC) and Constitution (CC) following the introduction of the Bill in the House of Lords in June. In particular, the committees have highlighted the following points:

- Clauses in the Bill on medical devices (Part 3, paragraphs 12-15) are broad and enable the Government to amend regulation or make new provisions in all areas covered in the Medical Devices Regulation (2002) **through secondary legislation**.
- These delegated powers in the Bill: *"…**give Ministers free rein to amend the regulatory regimes for…medical devices as they see fit.** By leaving almost everything about those regulatory regimes to be provided for by Ministers in regulations under the new powers–and little or nothing to be settled under the fuller scrutiny given to Bill provisions–the Bill could be seen as effecting a significant transfer of powers from the EU to Ministers, **bypassing Parliament**."* [House of Lords Delegated Powers and Regulatory Reform Committee (HL Paper 109), 19th Report of Session 2019–21. Medicines and Medical Devices Bill, paragraph 24, p. 6]

The UTA believes that the priority for Government would be to ensure that medical devices that are used in the UK are safe, clinically effective and of high quality. For this reason, any changes to the regulatory framework requires parliamentary oversight. There may be unique and urgent circumstances where the route of secondary legislation is appropriate but these should be time limited and be reviewed and debated by parliamentarians at later stages whose duty it is to hold the Government to account and ensure that all regulation is in the public interest.

- Furthermore, both committees have also raised how this is in effect a skeleton bill rather than an 'enabling' bill, as it was described throughout its passage in the Commons. The delegated and

emergency powers set out in the Bill effectively gives the Government unrestricted power to make policy and legislative changes through statutory instruments rather than through the process of parliamentary scrutiny. This top-down approach could not only result in more regulation and bureaucracy but it may have the unintended consequence of muffling the patient voice, with policies having little or no regard for patient rights.

- Indeed, the committee raises a crucial point about the power to create new criminal offences in the Bill: *"We have concluded previously that 'the creation of criminal offences through delegated powers is constitutionally unacceptable', save for exceptional circumstances.* ***The delegated powers to create and adjust criminal offences in this Bill are constitutionally unacceptable****."* [House of Lords Select Committee on the Constitution, 10th Report of Session 2019–21 (HL Paper 119). Medicines and Medical Devices Bill, paragraph 21, p. 4]

While the UTA believes that non-compliance of regulations should lead to tough sanctions, it is necessary to ensure that Parliament, with its collective knowledge and expertise, is involved in the process of shaping such legislation. There is the danger during health-related crises for authorities to knee-jerk under the pressure by imposing stricter rules and penalising medical device manufacturers and their suppliers. This will have a serious knock-on effect on the availability of innovative medical appliances that are clinically-appropriate to the patient.

Information systems

"The Secretary of State may by regulations make provision about the establishment and operation by the Health and Social Care Information Centre ("the Information Centre") of one or more information systems for purposes relating to…the safety of individuals who receive or are treated with a medical device, or into whom a medical device is implanted…"

The UTA supports the development of a register [Paragraph 16 (1) (a) – (c): 'Regulations: Information Systems'] for high-risk implantable medical devices. As revealed by Baroness Cumberlege in the Independent Medicines and Medical Devices Safety Review *First Do No Harm*, lapses in regulation and enforcement have resulted in serious untoward incidents in patients over a period of years. The establishment of a national registry to capture data will ensure that a tracking system is in place so that problems that have been identified can be resolved in a timely manner. It will also enable better patient follow-up during product recalls, post-marketing surveillance and clinical audit.

The UTA welcomes this development and will work with the Health and Social Care Information Centre (HSCIC) to ensure that appropriate standards and safeguards are in place in the establishment of registries. Consideration should be given to the way in which appliance user reviews (AURs) undertaken by Dispensing Appliance Contractors (DACs) can enhance information gathering and how these may fit into registers. However, the UTA would also like to highlight that the system needs to be simple to use and implement and not become a bureaucratic burden for manufacturers. Similarly, it would be useful for the Government to consider the administrative and other additional costs for manufacturers and their suppliers in the proposal for the HSCIC to capture and analysis data.

Clinical effectiveness

"…investigations into or evaluations of the safety or performance, including the clinical effectiveness, of medical devices…"

The UTA welcomes the emphasis in the Bill [Paragraph 13 (1) (i): 'Manufacture, marketing and supply']

on evaluating the clinical effectiveness of medical devices that are placed on the market. This provides peace of mind to clinicians and the users of medical devices. The clause supports innovation and demonstrates that products have undergone rigorous testing and they address the unmet need/s of patients.

The evidence on clinical effectiveness is also measured by health-related quality of life (QoL) impacts on people, as recognised by NICE in their health technology appraisals. QoL measures demonstrate that products are personalised to the user and are not generic. This prioritisation of the patient experience has had many health benefits for individuals using medical devices. The UTA would therefore like the Department of Health and Social Care and NHS to embed quality of life metrics in medical device assessments including in future Drug Tariff applications.

Sustaining the Drug Tariff

To support patient safety and choice, and to deliver transparency in price, it is important that the integrity of the Drug Tariff and the inclusion of urinary continence products on the list are considered when debating the Bill and considering any amendments.

At present, clinicians can prescribe and patients can access whichever medical device best meets their needs from the full range of products listed on Part IX of the Drug Tariff, the authorised list of urology and stoma products approved by the Health Secretary for prescription and clinical use on the NHS for all patients across England and Wales.

One benefit of the Part IX arrangements of the Drug Tariff is to provide protection for the NHS by clearly and consistently setting out prices for each product and protecting against overcharging, which ensures that medical device manufacturers and dispensing appliance contractors receive a fair price for their products. Products placed on the Drug Tariff are guaranteed to meet specific standards, notably that they are safe and of good quality, are cost-effective and are therefore appropriate for prescription. Maintaining the Drug Tariff will ensure that patients gain access to products with clinical oversight in the prescribing process and are not limited by local pressures to off-script prescriptions.

With midwives, physiotherapists, paramedics and other staff being able to prescribe patients with medicines and medical devices, it is essential that they are made aware of the full range of products available on the Drug Tariff while also receiving the appropriate training needed to offer prescription services. The UTA supports this approach as it will help widen patient access to care and enables quicker delivery of products to the patient with the wider use of electronic prescriptions on the NHS.

The UTA are concerned that the introduction of local formularies - short guidance documents developed by NHS Trusts and CCGs which set out a narrowed range of products that can be prescribed to patients by clinicians - risks confusing these important arrangements. Freedom of Information Act requests to all NHS Trusts and CCGs have found many have already introduced formularies or intend to do so.

We accept that formularies are here to stay but there is the danger that they may fragment access to new treatments on cost grounds and result in variation and inequalities across the different health economies. More importantly, we are concerned that formularies fail to signpost clinicians to the Drug Tariff and so discourage them from accessing it. This could lead to inappropriate restrictions on a clinician's duty to prescribe whichever product is most suitable for the patient.

With NHS Supply Chain looking to genericise products and introduce a national formulary, it is important that the Government ensures patient and clinical choice are maintained. Furthermore, a potential unintended consequence of a national formulary is that it becomes a major obstacle to innovation,

discouraging UK SMEs from entering the market. This is counter to the Bill's purpose to support the design, manufacture and distribution of medical devices by the UK life sciences sector in the post-Brexit landscape.

About

The Urology Trade Association (UTA) was established in 2007 to represent manufacturers and suppliers of urology products. The association seeks to:

- promote and protect patient choice in access to continence products;
- increase patient and public awareness about continence issues; and
- ensure that patients are not placed at adverse risk by ill-advised policy decisions.

Further information

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