Medicine and Medical Devices Bill 2020

Second Reading – Monday 2nd March

Briefing for Policymakers from the Urology Trade Association

An estimated 6 million people in the UK[1] (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 more midwives, physiotherapists, paramedics and other staff the power to prescribe what the Department of Health and Social Care described as "low risk medicines" which it said could help 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.

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 England and Wales 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 medical oversight in the prescribing process and are not limited by local moves 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

[1] (Source: Irwin, D., Milsom, I. et al. Impact of overactive bladder symptoms on employment, social inteactions and emotional wellbeing in six European countries. British Journal of Urology International: 2005; 97, 96-100)

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 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

Jordan Newfield
jordan.newfield@whitehouseconsulting.co.uk
+44 (0)20 7061 3204