Political briefing from the Urology Trade Association

Purpose

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

- promote and sustain 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.

1) Ensuring access to urology devices post-Brexit

There continues to be significant concern over the future of post-Brexit medical devices regulation.

Most of our members trade across the EU want to minimise any additional barriers or costs arising from Brexit. Regulatory divergence will lead to changes in licensing arrangements, which could mean increased bureaucracy for the civil service and manufacturers. This could increase duplication of work, decrease competitiveness and increase our operating costs. Some of our members import products and/or raw materials from either a single or multiple EU. New tariffs may have an impact on the price of products and the speed at which these goods can be delivered to UK customers. The UTA recommends that the Government ensures the continued smooth distribution of goods and services between the EU and UK.

To ensure a continuous flow of medical devices into the UK, it is essential that there is minimal disruption at ports and checkpoints into the UK. Urology products are essential for users to maintain a quality of life, and there are potentially serious personal health consequences if users do not receive their products on time.

2) Notified Bodies

The Medical Devices Regulation currently beginning to be implemented across the EU, imposes new burdens on those who assess and give approval of regulatory compliance for new medical devices. A combination of Brexit and those new burdens means that the capacity of the approval sector, through what known by the Medicines and Healthcare Products Regulatory Agency as Notified Bodies, is set to reduce by the end of the year. The reduction in notified bodies will lead to rising costs and lengthened delays. The Minister must address this if UK businesses in the medical technology sector are not to be significantly disadvantaged.

3) Sustaining the Drug Tariff

To support patient and clinician choice, and to deliver consistency in price, it is important that the integrity of the Drug Tariff and its inclusion of urinary continence products is maintained.

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 setting out prices for each product and protecting against overcharging, which ensures that manufacturers and developers can receive a fair price for their products and make financial plans for their futures. Products placed on the Drug Tariff are guaranteed to meet specific criteria, notably that they are safe and of good quality, are cost-effective and are therefore appropriate for prescription. Maintaining the Drug Tariff will ensure the patients are gaining access to products that have had a medical professional involved in the prescribing process and are not limited by moves to off-script prescriptions.

Clinical Commissioning Groups and NHS Trusts are under increasing pressure to find cost savings; and it is sometimes suggested that costs could be reduced if catheters no longer required prescriptions, thus, NHS equipment purchasers would hope that by purchasing larger batches of a narrower range of products the total cost could be reduced. Not only does this curb patient access to care, but it also creates health inequalities and can lead to urinary tract infections if the product used is not ideal for an individual patient, again driving up treatment costs. The removal of the need for a prescription would leave some of the most vulnerable patients in jeopardy. This practice, and the introduction by some NHS Trusts of local formularies (a more limited list of available products), risks some patients and their clinicians not being made readily aware of the full range of products available on the Drug Tariff.

In this context, there is a clear need for commissioners within CCGs and purchasers within Trusts to be properly supported in understanding patient rights as outlined in the NHS Constitution in relation both to the quality of care and access to the full range of products.

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. However, 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 introduce a national formulary, it is important that the Government ensures patient and clinical choice is sustained.

4) Plastics and reusables

We understand that officials at NHS England have been approached to discuss the potential return to the dark ages of re-usable catheters and the associated sterilisation techniques. We are concerned by this development, given that NICE[1] considers Intermittent Self-Catheterisation (ISC) as the Gold Standard in urine drainage and for reducing the risk of infection. Existing Royal College of Nursing guidelines also state clearly that to prevent infection, single-use catheters should never be reused.[2]

[1] https://www.nice.org.uk/guidance/cg171
[2] RCN (2019) *Catheter Care. RCN Guidance for Health Care Professionals* https://www.rcn.org.uk/professional-development/publications/pub-007313

Our understanding is that this project is being pursued to reduce plastic waste in the health system and to save on costs. We recognise that these are two important priorities for the NHS and our members work closely with the NHS and procurement managers in the search for solutions. Re-using a catheter that has been sterilised by hand, however, is likely to be a dangerous move which puts patient safety at risk:

- There is a risk that a return to re-usable catheters and sterilisation techniques may increase the rate of urinary tract infections (UTIs) in the UK. In 2013/14 (the last year in which these figures were available) the unplanned admissions for UTIs cost the £434 million per year.[3] UTIs also put vulnerable patients at risk of further health complications, including renal failure and death.

- Single-use catheters provide those with long term continence needs, including those with disability and mobility issues, with a patient-centred and discreet way to manage their conditions. The sterilisation of catheters for re-use is not a practical or safe option for many patients and would require significant lifestyle changes that could be disruptive.

- There are serious legal questions about how sterilisation techniques under development could be used on catheters legally marked for single use only. Sterilising single-use catheters for reuse would effectively be illegal and it would be illegal for healthcare professionals to recommend this practice.

UTA members acknowledge that plastics waste is a problem, and are reviewing their own supply chains to reduce their carbon footprint and reduce their single-use plastics waste in the manufacturing of continence products.

Further information

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[3] £434 million spent on treating unplanned UTI admissions, 23 January 2018.
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