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) 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 clearly state that to prevent infection, single-use catheters should never be reused.[2]

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 sepsis.

- 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 and ethical 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 be against the MHRA, and clinicians would be liable for any adverse effects on patients if they recommend this practice. MHRA guidance on this can be found here.

[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
[3] £434 million spent on treating unplanned UTI admissions, 23 January 2018. https://static1.squarespace.com/static/5638ec80e4b0b4604ee0e0e5/t/5a01ac328165f56ac4b2eeb3/1510059080322/Unplanned+Admissions+Consensus+Committee+-+Best+Practice+Guide.pdf

UTA members acknowledge that plastics waste is a problem that requires longer-term investment by the government and manufacturers. Our members are reviewing their own supply chains to reduce their carbon footprint and plastic, specifically single-use plastic packaging.

2) Post-Brexit Medical Device Regulation and Notified Bodies

Now that we have left the EU, changes have been made to how medical devices, including urology products, are placed on the market in Great Britain. CE marking will continue to be recognised in Great Britain until 30 June 2023, but the new UKCA mark is now being phased in to replace the CE mark. The UKCA mark alone will not be recognised in the EU, so any exports from the UK to the EU will also need to meet EU standards and bear the CE mark.

Separately, under the terms of the Northern Ireland Protocol, the rules for placing medical devices on the Northern Ireland market differ from the rest of the UK. CE marking will still be required in Northern Ireland, but a UKNI will be required for devices if they have been approved by a UK Conformity Assessment Body (CAB). The below table outlines the different scenarios and the accepted markings in more detail.

Scenario	Accepted Markings
Placing devices in the NI market using an EU CAB	CE
Placing devices in the NI market using a UK CAB	CE and UKNI
Placing devices in the Great Britain market until 30 June 2023	UKCA and CE
Placing devices in the Great Britain market from 1 July 2023	UKCA
Placing goods in the EU market by an NI manufacturer	CE
Placing goods in the Great Britain market by an NI manufacturer	CE or CE and UKNI
Placing goods in the EU market by a Great Britain manufacturer	UKCA and CE

The UTA supports a position of close regulatory alignment with the EU, and would encourage the MHRA to work closely with international partners to harmonise standards when developing its own regulatory policy. Regulatory divergence across the UK, EU and elsewhere, could lead to increased bureaucracy for the civil service and manufacturers. This could increase duplication of work, decrease competitiveness and increase our operating costs. Inconsistencies in regulatory policy between the UK and elsewhere could burden manufacturers of urology products, so effective international regulatory cooperation and harmonisation should be a policy-making priority.

The EU no longer recognises UK Notified Bodies, so an EU-recognised Notified Body will be needed to undertake any mandatory third-party conformity assessment to place products on the EU market, perhaps leading to rising costs and lengthened delays. Similarly, UK Notified Bodies will not be able to issue CE certificates, and an EU-recognised Notified Body will be needed to undertake any mandatory third-party conformity assessment. To ensure the continued approval of medical devices/medical products in the UK from elsewhere, the UTA recommends close collaboration between UK and EU notified bodies, to allow for the fast approval of products in the UK, thus ensuring that there is no disruption in obtaining new and innovative urology products for patients.

The UTA recommends that the government guarantees the continued smooth distribution of goods and services between the EU and UK. To maintain the continuous flow of medical devices into the UK, there needs to be 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.

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 receive a fair price for their products and make financial plans for their futures. Tariffs on imported medical devices are absorbed by manufacturers and distributors. These additional costs are not passed on to the NHS or payers as the price for each medical product is listed on the Drug Tariff. This helps the NHS to plan and predict its spend on continence products. 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 variation across regions and health inequalities and can lead to poorer patient outcomes if the product used is not suited to 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 are sustained.

The UTA, working closely with the Drug Tariff Committee (comprising the other trade associations – the ABHI, BHTA, BIVDA and SDMA), has published a position paper on the Drug Tariff which has been shared with NHSBSA. This paper can be viewed here.

Further information

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