Political briefing

The UTA is a strong supporter of the principle that a clinician should be able to prescribe, and a patient to have access to, whichever medical device is most clinically appropriate. There should be no acceptance of one, or a small range of devices being suitable for all when it comes to urology products. The approach should be to deliver "value for money" within NHS procurement, rather than focusing on item price. This ensures that products provide the best patient and clinical outcomes. However, well intentioned initiatives taken forward by a number of different stakeholders risk delivering a different reality, in which NHS procurement in the sector might focus too much on driving costs down without considering the wider impacts on patients and on the wider NHS system.

1) Med Tech Directorate

In 2021, the Government launched a new MedTech Directorate within the Department of Health and Social Care (DHSC) to focus on Britain's leading position in MedTech research and innovation. This new Directorate is focusing on the increasingly important role medical technologies are playing in the prevention of ill health and the diagnosis and treatment of disease, assessing how we regulate, commission and use them on an ongoing basis.

In February 2023, the Directorate published its Medical Technology Strategy. We welcome the strategy as a positive development for MedTech innovation and research and the regulation of safe, high-quality products. However, the Directorate must develop a clear definition of 'innovation' and ensure that it does not lose sight of patient safety and outcomes; both of which should remain a primary focus to industry, government, and clinicians. For this to hold true, innovation of all kinds, whether it be incremental or step-change, should be encouraged and valued.

The UTA will work to ensure that the Directorate continues to engage with industry, clinicians and patients. This includes considering the interests of patients with urological conditions and the professional judgement of clinicians who work in the urology sector.

Primarily, the UTA want to ensure that **the Directorate are aware of the importance of sustaining Part IX of the Drug Tariff**.

2) Sustaining the Drug Tariff and Part IX

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 have the right to 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. However not all clinicians or patients are aware of this right.

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 how much is spent on continence products.

Products placed on the Drug Tariff must meet specific criteria, be safe and of good quality, are cost-effective and are therefore appropriate for prescription. Maintaining the Drug Tariff will

ensure 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.

Following the proposals on reviewing Part IX, UTA is concerned that the outcome of these proposals could potentially deny patients access to the clinically most appropriate product for them, restrict clinicians' freedom to prescribe the full range of products available, and undermine the businesses which supply these products to the NHS.

Part IX is already very clear for clinicians, and it is up to these professionals to guide product usage. It is not the job of the Drug Tariff to make decisions on what is best to be prescribed for the healthcare needs of patients. Allowing the Drug Tariff to restrict decisions on prescriptions for patients risks compromising personalised care. Clinicians should work in conjunction with patients and establish the most appropriate treatments, ensuring high-quality healthcare and in turn decreasing whole system costs.

The NHS 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 leading to poorer patient outcomes and readmission if the product used is not suited to an individual patient.

Furthermore, significant changes to the infrastructure of the Tariff could result in appeals and challenges from businesses, which could disrupt the supply of products to patients. The proposals show little understanding of the certainty that companies and investors need when they plan for their pipeline and/or product launches in the UK, and there are concerns that any changes to the Tariff could create a less resilient supply chain. Companies may choose to launch future innovative products in markets offering greater certainty, and in some instances may be forced to withdraw from the market completely, so impacting patients.

Ultimately, whilst the aim of the consultation is to help the department achieve best value and encourage the use of good quality and cost-effective medical devices (appliances) for patients, these proposals do not align with the needs of patients and disrupt the Drug Tariff's stated purpose of providing the full range of authorised products available for prescription and clinical use. This could lead to patients not receiving the right product for their individual need, leaving the most vulnerable patients in jeopardy.

The consultation on Part IX of the Drug Tariff was launched in October 2023 with the government response shared to the industry in August 2024 – please note that this consultation was not publicly available and therefore a link to the original questions to the consultation is not provided.

As a trade association representing industry members, we have been involved in DHSC's process of implementing the changes to Part IX addressed in the consultation by reviewing the current product categories and defining new ones. At present, we are aware that DHSC has shared its Quality and Social Value and Evaluation frameworks for Part IX with stakeholders for comments and feedback, due to be submitted in January 2025.

3) MedTech Pathway

In May 2024, NHS England and NICE also published proposals on the establishment of a MedTech Pathway. While the UTA do not disagree with the proposals, it is concerned that if the mechanisms of

the pathway are too heavily influenced by price savings and cost-effectiveness, it might lead to a situation in which patients are not provided with the most appropriate MedTech to suit their individual needs.

There should be more focus placed on the importance of funding for technologies that actually deliver significant patient and clinical outcomes, and more consideration should be given to the impact of products on patients, carers and the wider and social economy. By looking at not simply which technology or product is cheapest, but also at which is best for patient outcomes and quality of life, leads to a substantial reduction in overall health and care system costs – whilst significantly reducing demands for additional treatments and alleviating NHS capacity. For instance, high quality and safe urology appliances allow users to manage their conditions, maintaining their quality of life and allowing them independence and avoiding repeated medical consultations.

The UTA is currently anticipating the government response to the MedTech Pathway consultation.

4) Ensuring best practice in continence care

With demand for urological products expected to rise in the next decade, the provision of high-quality and personalised continence care across the UK has never been more important.

With NICE currently undertaking a late-stage assessment to "provide guidance on value" for technologies in widespread use within the NHS, the UTA is concerned on the impact that such assessments will have on the procurement of clinically appropriate products for patients. By potentially limiting the range of products within a given category, this could lead to thousands of well-treated chronic patients being shifted to other, less clinically appropriate products. To ensure best practice in continence care across the system, stakeholders should remember that patient choice and outcomes must be at the forefront of any definition of value, ensuring seamless access to the most appropriate technology to meet their individual need.

Annex

Urological and continence care in the UK

Urological diseases include some of the most common medical conditions in the UK, including urinary tract infections and urinary incontinence. It is estimated that 14 million people in the UK have some degree of urinary incontinence (over 21,000 on average in each parliamentary constituency), approximately 50,000 people in the UK use intermittent catheters, and every hour, 7 people are diagnosed with urological cancer. Given the unfortunate stigma surrounding these issues, incontinence can often go undiagnosed, with many patients reluctant to raise symptoms with healthcare professionals, or even to family and friends. But, poor continence care can increase risk of infection, loss of dignity, social isolation, as well as avoidable admission to nursing homes or hospital.

Given the prevalence of these conditions, many people are reliant on good-quality continence care and services and depend on continence products on a regular basis. High quality and safe urology appliances allow users to manage their conditions, maintaining their quality of life and allowing them independence and avoiding repeated medical consultations.

About

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

- promotes and sustains patient choice in access to continence products;
- increases patient and public awareness about continence issues; and
- ensures that patients are not placed at adverse risk by ill-advised policy decisions.

Further information

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January 2025