Political briefing

The Urology Trade Association

The [Urology Trade Association](https://urologytradeassociation.com/) (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. Med Tech Directorate

In 2021, the Government launched a new Medical Technologies division within the Department of Health and Social Care (DHSC) to focus on Britain’s leading position in med-tech 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. The new directorate will focus on six main areas: resilient supply chains; value for money; regulation of safe, high-quality products; sustainability; innovation to improve clinical outcomes; and promoting UK interests in global markets.

The UTA are engaging with the Directorate, as it continues to define its objectives, priorities and workstreams. The UTA will work to ensure that the Directorate continues to engage with industry, clinicians and patients during the implementation of its forthcoming strategy. This includes taking into account 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, for the reasons set out below in the section below.

1. 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 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 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 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.**

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. Urinary tract infections (UTIs) put vulnerable patients at risk of further health complications, including renal failure and sepsis, which also drives up treatment costs.

Removing the need for a prescription would leave 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 patients and their clinicians not being made readily aware of the full range of products available on the Drug Tariff.

1. Post-Brexit Medical Device Regulation

Now that we have left the EU, changes to how medical devices (such as urology products), are placed on the market in Great Britain (GB), is of grave importance to UTA Members. In June 2022, the Government published its [response](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1085333/Government_response_to_consultation_on_the_future_regulation_of_medical_devices_in_the_United_Kingdom.pdf) to its consultation on the future regulation of medical devices in the UK. It set out the Government’s intention to align the new regime with the EU’s in areas such as expanding the scope of regulations and obligations concerning traceability. In other specific areas, the Government plans to diverge the GB market away from the EU.

The UTA argues that **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.**

Due to the Northern Ireland (NI) Protocol, medical devices moving from or through GB to NI are considered an import into the EU and are therefore subject to the EU Regulations and further checks. 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 if patients do not receive their products on time, this could drive up treatment costs in the long-term.

Further information

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