Response to NHS Chief Executive’s Open Call for Evidence and Ideas

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A response from the Urology Trade Association

The Urology Trade Association
The Urology Trade Association (UTA) represents up to 95% of manufacturers and service providers who supply the urology appliance market. Our members make products including catheter, leg bags, sheaths, and other products which help people to manage their continence problems.

An estimated 6 million people in the UK are affected by continence problems, often due to complex long term conditions such as spinal cord injuries, cancer or neurological conditions such as MS. High quality urology appliances allow users to manage their conditions, maintaining their quality of life and independence and avoiding repeated medical consultations.

Innovation is vital within the urology sector to provide new products which improve the quality of life for patients and save money for the NHS as well as the wider public sector. Many of our members also make stoma products, where many of the issues with regard to innovation are similar; therefore this response will also draw on examples from this sector.

Our aims are to:
• act as a forum for discussion and a vehicle for collective action on all issues relating to the urology product manufacturing and/or distributing sector
• represent the interests and consensus opinion of our members
• promote the contribution to NHS patients of the urology manufacturing sector and its products
• communicate the benefits of high quality, innovative urology appliances to key stakeholders
• work in collaboration with Healthcare Professional bodies and patient organisations

This response will outline how innovation is currently adopted and diffused within the NHS, along with specific suggestions as to how this system could be improved. The UTA supports the view of the Department of Health and believes that the Drug Tariff offers a recognised and efficient route for the adoption and diffusion of innovation.

Background
In primary care, urology and stoma appliances are supplied to patients in England and Wales on prescription through pharmaceutical services under The new arrangements under Part IX of the Drug Tariff for the provision of stoma and urology appliances – and related services – in primary care. These arrangements have been subject to a lengthy series of seven public consultations in recent years. As a result of this exercise, the Department of Health concluded that the Drug Tariff is the preferred mechanism to improve patient care, maintain local choice, and provide services and products at a fair and balanced cost to the NHS and industry; prices were reduced and changes implemented from 1st April 2010.
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Part IX of the Drug Tariff
The list of appliances approved by the Secretary of State for Health for prescription in the community at the expense of the NHS appears each month in Part IX of the Drug Tariff for England and Wales. This also lists the price that the NHS should be charged for each urology appliance (reimbursement) and each service provided by dispensers in the community (remuneration). The prices for both these elements are set centrally by the Secretary of State. Where appropriate, price increases for appliances are managed centrally by NHS Business Services Authority Prescription Services.

Patients are prescribed urology appliances from the Part IX list by GPs or qualified prescribing nurses and are issued a FP10 prescription form. Patients are able to take the prescription to any Dispensing Appliance Contractor or Pharmacy Contractor of their choice to have the item dispensed. If no suitable contractor is available they may use a Dispensing doctor.

As a result of the new Part IX arrangements, dispensing appliance contractors must now provide the following as part of essential services:

- Repeat dispensing service
- Dispensing referral
- Urgent supply without a prescription
- Home delivery service and supply of wipes and disposal bags

A separate, more diverse pricing system operates in secondary care

Routes to innovation
One of the key advantages of the Drug Tariff is the way it offers a recognised route for the adoption and diffusion of innovation.

Innovation is particularly relevant for the urology sector given the impact that advances in product design, specification and technology have on improving quality of life, potential for self-care, mobility and ability to live an independent working or social life. Up to 150,000 people across the UK depend on urology products and care, many of whom require continence management as a result of any number of conditions such as spinal injury, cancer or neurological degenerative disorders.

As a result of advances in medical and clinical care, in the coming years there will be an increasing number of elderly people managing long term conditions which require continence management in the community. This demographic group will present clinicians, manufacturers and suppliers with a new range of needs that will challenge product innovation and development. Equally, the paediatric urology sector is continually dependent on niche and innovative products in this area of care.

The Drug Tariff is an appropriate mechanism to bring products to market and is more receptive than the alternatives to the uptake and diffusion of new products across the NHS. By paying manufacturers a fair price for their products while guaranteeing the NHS value for money, it ensures that a full range of products is available to meet the diverse needs of patients.
Many prescribers look to choose products on the basis of cost. However, when even minor differences in products can make a big difference to patients’ lives, there need to be mechanisms in place which allow the wider health and social costs of inappropriate provision to be taken into account.

**Case study: The route to market for urology and stoma products**

The following case study covers Peristeen, a bowel irritation system developed by one of the UTA members. This case study illustrates the potential impacts for innovation in this area and the advantages of the Drug Tariff for the adoption of innovation within the NHS.

**What is Peristeen?**

Peristeen is a major innovation in bowel irrigation, which works by introducing lukewarm tap water into the bowel using a rectal catheter. The research and development phase included a five country randomised control trial comparing Peristeen to conservative bowel management methods.

**What is innovative about Peristeen?**

A number of other methods are used for individuals with faecal incontinence including enemas, laxatives, and suppositories. For conditions such as spinal cord injuries and spina bifida, manual evacuation is often used, which for some people can take several hours, and has obvious implications for the dignity of patients.

The research carried out during the development of Peristeen showed that Peristeen led to reduction of faecal incontinence, reduction of constipation and increased independence. It is particularly useful for people with low manual dexterity, such as those with spinal cord injuries, and can lead to a significant increase in dignity and the ability to lead a normal life.

Peristeen is a complete innovation in bowel management, developed using robust evidence. As it was the first product of its kind, it required a significant investment in research and development.

**Cost**

The initial starter kit costs around £70. The frequency with which Peristeen is used varies from patient to patient, but the most common frequency is every other day – this would require catheters on prescription costing around £1600 a year. While Peristeen is more expensive than alternative products such as laxatives, it can save money in other areas, including reduction in nursing time required (for some patients from seven days a week to one day a week). There is also evidence of reductions in urinary tract infections for those using the products, something which also has large cost implications.

The average cost for the admission of emergency urethral catheterisation resulting from infection is estimated in the region of £1,500 per patient, per visit. In addition, if patients are forced to change products, they must first be clinically assessed before being prescribed with alternatives. In specialist care, the associated and potential costs of such procurement initiatives are a considerable expense for PCTs and could potentially far outweigh any initial savings.
However, these savings are often not taken into account when making decisions about prescribing products – most likely because they would not lead to savings from the prescribing budget itself.

In addition, the fact that using this product allows many people to become more independent means that they are able to manage their own care and may be able to return to work – creating huge savings for the welfare system which are not generally factored into health budgets. The adoption of innovation within the NHS is not important just to improve the quality of patient care, but also to ensure that improved outcomes and savings in public spending can be made across all policy areas.

Cost-effectiveness of transanal irrigation versus conservative bowel management for spinal cord injury patients (P Christensen, J Andreasen and L Ehlers), published in Spinal Cord (2009) 47, 138–143 demonstrated the overall costs to the public purse of using this product were cheaper, due to the reasons outlined above.

Patient Experiences
Peristeen has made a real difference to the lives of some patients, showing the positive effects of innovation within the medical device sector. The following testimonial is from a nurse looking after a 29 year old man with progressive MS.

“He was having horrendous problems with Faecal Incontinence and alternating constipation to the point of not being able to go out of the house for the past 4 years. He had been seeing a psychiatrist as he was threatening suicide because he felt life wasn't worth living, and wouldn't have any visitors to the house because he felt he was smelly.

He's now been using Peristeen for the past 3 months and sounds like a completely different person to talk to. He says it's a "God-send" and can't believe how easy it is to use. It takes him around 10 minutes every morning and then he's been taking his daughter to school for the first time ever and going out for lunch with his wife. He's even just booked a family holiday for them all!”

How are products approved for inclusion on the Drug Tariff?
In order to get a product approved for use in primary care, companies must apply to have the product listed on the Drug Tariff, providing costings and evidence to support efficacy and justify the price.

The process is generally straightforward if the products cost less than the existing products, but for higher priced products it is necessary to provide robust justification as to why the price is higher. Positive user evaluations are usually helpful in getting a product listed.

Once the evidence is submitted, officials may go back to the company and ask for any further information which is deemed necessary. Assuming the products fit into an existing category, it generally takes three to six months for a new product to be approved. For changes to an existing category, it would take less time, while an entirely new category would take longer.
How are products marketed and what are the barriers to diffusing innovation?
Marketing a product generally involves mail shots to healthcare professionals, advertising in journals and sending sales people to demonstrate the new product.

One issue that has been raised as a barrier to diffusing innovation is the fact that many nurses are no longer able to meet company representatives, which is the main way of finding out about new products. Nurses themselves have commented that, without being able see new products and understand how they work; it is unlikely they will be able to recommend them to patients, even if it could be the best product for their needs.

There is a perception that information sessions are used to influence nurses and other healthcare professionals, but there is no evidence to support this. More trust needs to be put in nurses to make the right decisions for their patients, bearing in mind the cost implications.

What are the advantages of the Drug Tariff in supporting innovation?

- The Drug Tariff is an approval process which is universally recognised by the healthcare profession, guaranteeing safety, effectiveness and value for money, and hence allowing them to trust the available products.

- The Drug Tariff is designed to ensure universal access to products for patients no matter where they live, something which will become very important as decisions about healthcare are increasingly made on a local basis.

- The Drug Tariff looks beyond the price of the product at the wider benefits and added value it can offer, while demanding robust evidence to allow higher prices to be charged. Therefore, it ensures value for money while allowing patients access to new and innovative products which meet their individual needs.

- The NHS Supply Chain framework used in secondary care makes it very difficult to add a new product if a company is not already listed, or to add new categories of products. The Drug Tariff provides a recognised route for doing this.

How would innovation work without the Drug Tariff?
Currently NHS Supply Chain (run by DHL) is considering, subject to a report from the NHS Business Services Authority, introducing an off-script home delivery service for continence products, something which could potentially work to undermine the Drug Tariff and reduce the quality of patient care, due to their dominant position in the market and the fact that they are able to use the NHS logo. Currently they supply products into the acute sector, which is a very different market to the primary care sector due to the absence of the Drug Tariff.
Product innovation and development depends on there being multiple providers and competition in the marketplace, and there are concerns that the proposals from NHS Supply Chain could undermine some of the smaller suppliers in the market. The NHS Supply Chain tender tends to focus on the costs of products, rather than the wider value which they provide.

Additionally, one of the flaws with the NHS Supply Chain model, as it is used in secondary care, is that no new products could be added to the contract unless the company is already listed as part of the tender. This would be a major obstacle to encouraging new suppliers into the marketplace and ensuring that the marketplace is flexible enough to support and implement future innovations and inventions in the sector. In contrast, the Drug Tariff has proved to be flexible in terms of adding new categories. It is unclear if this could be replicated in the NHS Supply Chain model.

The centralised approval system of the Drug Tariff ensures that new products are fully evaluated in terms of appropriateness for use in the community, safety, quality, clinical effectiveness and cost before they can be listed. Only once this process is satisfied that these criteria have been met can the products be made available. For new products, this not only minimises the costs to the NHS of adopting new technologies by avoiding replication of the approval process across individual procurement agencies, but it also minimises the costs to industry for the same reasons. Considering that initial costs for new products are very high, replicating approval processes would have an impact on the final cost of the products to the NHS.

The Drug Tariff also places an obligation on manufacturers to ensure that any listed products are continually available and can be used anywhere in the country. This is of benefit to the NHS in terms of securing diffusion of new products across the NHS.

Specific recommendations
The UTA has specific recommendations for action which could be taken to improve the adoption and diffusion of innovation throughout the NHS.

Actions at national level in the NHS

- **Maintain the Drug Tariff** as an appropriate mechanism for the evaluation of new products on the basis of value for money and offering a route for the diffusion of products through the NHS. As the Drug Tariff is well understood by the industry and healthcare professionals, it offers a common method of understanding pricing decisions and provides reassurance that products are safe, effective and provide value for money. This is something that will be increasingly important as the NHS becomes more localised.

- **Ministers and officials should offer a strong message of support for the Drug Tariff.** At the moment, the Drug Tariff is being undermined by the use of individual tenders and formularies by PCT commissioners and procurers and by developments such as the move of NHS Supply Chain into the community sector. The Department of Health should be sending strong signals that they support the principles of the Drug Tariff.
• **Engagement with industry to resolve any ongoing issues.** We understand that some of the ambiguity about the Drug Tariff may come from concerns within the Department of Health about particular aspects of the Drug Tariff. However, we feel strongly that the Drug Tariff is the best system to ensure innovative products continue to be produced and adopted, and would be very keen to work with the Department of Health to find solutions to ongoing issues. We have already begun proactive work to identify and address perceived problems, and are in the process of producing a detailed report on this issue. We very much hope that the Department will want to discuss this once finalised.

• **Incentivise commissioners to think about the wider costs of inappropriate prescribing.** There can be a tendency for those involved in procuring and prescribing products to only look at the impact of prescribing a product on their own budget. However, as we have highlighted in this document, the inappropriate prescription of products can lead to a range of problems, from an increased likelihood of UTIs to a lack of independence and inability to work, all of which have impacts on other areas of public spending. This is fairly understandable – commissioners are not always praised for decisions which cost them more money but save money elsewhere. The Government needs to think about how commissioners can be incentivised to think about the overall costs of their decisions across the entire area of public spending.

• **More recognition could be given to NHS bodies such as the NHS Technology Adoption Centre, which undertakes independent reviews to assess the capability of new technologies to allow the NHS to save money.** Members have commented that even when they have had products reviewed, there have still been difficulties in encouraging adoption because the initial cost is more expensive than traditional products – despite the huge cost savings associated with them over the longer term.

**Actions at local level in the NHS**

• **Local commissioning organisations should respect the Drug Tariff** and not try to undermine it with the use of formularies or other methods of limiting the products available. All products which have been listed on the Drug Tariff have been shown to provide value for money, and decisions about which product to provide to a particular patient should be taken on an individual basis, taking into account the needs and wishes of the patient – respecting the strengthened requirements for patient choice requested by the NHS Future Forum.

• **Ensure that nurses and other healthcare professionals are able to learn about new products.** The consultation document notes that NHS staff want to provide the best care for their patients, which often means the latest treatment and technologies. It also notes that for innovation to spread, NHS staff need access to the best available information and evidence. However, as we have mentioned above, many nurses and other healthcare professionals struggle to find out information about new products because local NHS organisations have prevented them from meeting with device companies. Nurses themselves have commented that there are fewer
opportunities to learn about new products, which means that they are unable to find out if there is a product which best meets patient needs. This acts as a real barrier to the diffusion of innovation and leads to a variable quality in service due to differing rules across the country. Nurses need to be trusted to make the best decisions for their patients, based on a full picture of the available products.

- **Consider if there are better ways of delivering services and products.** The continence service run in Rotherham is innovative in the way in which it delivers services to patient. Rather than contacting their GPs directly, patients now contact the continence service, run by specialist continence nurses, to request prescriptions for continence products. Clinical reviews are a core element of the new service. Every time a prescription is ordered, a telephone triage is carried out, with the prescription coordinator asking questions about issues such as UTIs, skin soreness, and product performance and faults. If problems are identified, patients are referred to the continence nurse specialist, to ensure a clinical review is undertaken before further products are issued. This has the effect of maintaining patient choice of products – and thus allowing room for innovative new products to be prescribed – while saving the NHS money through reducing prescription of inappropriate products and reducing wastage through unnecessary repeat prescriptions. Significant savings have been achieved. This demonstrates that services can be designed to ensure best value for NHS money while allowing patients access to innovative products which can help them better manage their conditions and which may have positive effects on other areas of public spending.

- **Local organisations should consider how to incentivise better prescribing.** Prescribing an inappropriate product to a patient may save money from a prescribing budget while costing further money to the local NHS if it leads to a UTI. As well as looking at how smarter prescribing could be incentivised on a national level, work should be done to determine how this could be achieved on a local level, perhaps with several trusts and PCTs or GP consortia working together.

**Actions by NHS partners**

- **The industry should work with the Department of Health to deal with ongoing issues,** for example to address concerns about the Drug Tariff. This would allow issues to be addressed to improve the operation of the system, while maintaining the benefits it offers. As mentioned above, the UTA is very happy to engage with the Department of Health on these issues.

- **Patient groups should work with industry and the Department of Health to ensure that their voices are heard and to improve the quality of services.** We have worked with the Urology User Group Coalition who has been very proactive at engaging with health services to ensure that decisions are taken in the best interests of patients.

**Conclusions**
This response has set out the view of the Urology Trade Association on the strengths and weaknesses of the current system for supplying urology and stoma products, and how this impacts on the adoption and
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diffusion of innovation. While we believe that the current system is broadly beneficial, we have highlighted a number of ways in which we think improvements could be made, including action from the NHS, industry and patients.

We would like to reiterate that we are very keen for constructive dialogue with the Department of Health to ensure that problems can be addressed as they arise, to the benefit of all stakeholders.