INDUSTRY POSITION PAPER

FP10 route for the supply of appliances in the community setting in England & Wales

Introduction and Background

The Part IX Industry Drug Tariff Committee was formed in the early 1990s to represent Companies with appliances listed in Part IX of the Drug Tariff. The Committee is comprised of representatives of all the relevant Trade Associations. Currently these are the ABHI (Association of British Healthcare Industry), BIVDA (British In-Vitro Diagnostics Association), BHTA (British Healthcare Trade Association), SDMA (Surgical Dressings Manufacturers Association), and UTA (Urology Trade Association). It takes its mandate from all relevant companies, whether they are members of the Trade Associations or not, from the Part IX Industry Drug Tariff Forum.

The headline mandate is shown below (more specific remits are gained at meetings of the whole Forum which are held from time to time):

- To provide a common voice between industry and relevant government departments involved in the Drug Tariff (hereinafter referred to as DT) on issues which are industry wide.
- To monitor the performance of the DT with regard to the application process.
- To use its influence to ensure the price increase mechanism is adhered to by industry and specifically to engage with the DT in agreeing an appropriate level of factor X.
- To provide industry with information concerning the DT that may impact their business.
- To negotiate with the DT on specific issues raised by the Forum.

The purpose of this paper is to set out the advantages of a transparent, centrally negotiated and policed system where essential appliances (at the discretion of the Secretary of State for Health) are listed in Part IX of the Drug Tariff, prescribed on form FP10 and dispensed by appropriately qualified contractors. This enables the NHS to maintain a uniform high standard of healthcare for these vulnerable minority patient groups who rely on using those appliances in a community setting.

The Supply of Appliances through Pharmaceutical Services

The list of appliances deemed appropriate by the Secretary of State for Health for use in the community at the expense of the NHS appears each month in the Drug Tariff for England and Wales. General Practitioners and suitably qualified nurses issue a patient with an FP10 form and the patient is free to take that prescription to a Contractor of his choice to have the items dispensed. Appliances listed in Parts IXA/B/C can be dispensed either by a Pharmacy Contractor or an Appliance Contractor. Both offer essential and advanced services. Where a suitable contractor is not available a dispensing doctor may be available. All other items supplied through pharmaceutical services including drugs and reagents listed in Part IXR, the patient can choose which Pharmacy Contractor best suits his/her needs

The prices for those appliances listed in Parts IXA/B/C and Reagents listed in Part IXR are set centrally with price increases where appropriate managed centrally by NHS Business Services Authority Prescription Services.

The industry Drug Tariff Committee believes that this centralised system operated on a local basis is the best way of patients obtaining appliances in a community based setting for the following reasons:

(We have divided our reasons for using the Drug Tariff and FP10 as the preferred means of supply of appliances in the community into four headings: Choice, Cost/Value for money, Quality of products, and Losses to the NHS if the centralised system were abandoned.)

A Choice

- The centralised system ensures that product is available regardless of where the patient lives - post code prescribing would result if localised negotiation took place.
- Specialist products/services, even those used by very small numbers of patients are available nationwide would vary and could be lost as patient numbers are low.
- Patient has choice of both clinician and contractor this would be lost if local arrangements specify only one supplier.
- Product customisation is currently offered as an advanced service by most Dispensing Appliance Contractors (DACs) – this may be lost if local tenders are followed.
- Personalised home delivery. The Trading Standards Institute approved BHTA Code of Practice ensures DACs carry this out.
- The centralised system ensures that products from different manufacturers are made available. This competition maintains multiple suppliers.
- Services provided by DACs and PCSs are controlled by central rules applied locally loss of central control would result in variability of service locally.
- The current system is well understood and easy to use.
- In the absence of Parts IXA/B/C/R the current transparent pricing would be lost to varying prices which would not be comparable due to lack of centralised co-ordination and policing.
- Clinicians have the choice of any of the appliances deemed appropriate by the Secretary of state for Health.

B Cost / Value for money

- Pharmaceutical services have preferential VAT treatment for Commissioners.
- The current system has a low cost of administration.
- Multiple manufacturers mean competitive pricing.
- Service provided by DACs/PCSs is paid for through the global sum –this has not always been included in local tenders.

- No warehousing or logistic costs under the current system through pharmaceutical services, as stock is held by Contractor until needed by patient.
- Stock remains property of the contractor so Commissioners are not exposed to costs associated with returns or expiry date issues.
- No NHS employment costs relating to distribution and dispensing.
- Pharmaceutical services provides for split bulk resulting in wastage eliminated or controlled.
- Centralised control of pricing e.g. no price increase for 4 years and 2% reduction on 1° April 2010.
- Central NHS ownership of system would be lost if centralisation where abandoned.

C Quality of products

- Innovation from competition and patient feed-back because of direct contact by Contractor with users and patients,
- Drug tariff approval system based on appropriateness, safety, quality, efficacy and cost effectiveness.
- Consistent availability of product is part of current system.
- Maintenance of supply of low volume specialised products.

D Centralised system (operated on a Local Basis)

- Availability of prescribing data.
- Centralised price setting/price control.
- Centralised decision on availability based on tests of safety quality efficacy appropriateness and cost effectiveness.
- Transparency of pricing and costs of supply/service.
- Electronic prescribing.
- Education.
- Centralised service standards policed on a local basis.
- Current system is the result of 3 ½ years of consultation.
- Decentralised system with central control.
- Avoidance of monopoly supplier situation.

In conclusion, the Industry Drug Tariff Committee believes that the pharmaceutical services route of supply of appliances is the most appropriate for reasons of:

Choice: to both the patient in terms of choice of clinician and contractor, and to the clinician in terms of selecting the most appropriate product from the list approved by the Secretary of State for Health.

Cost: both in terms of Commissioners not having to pay for goods until after the patient has used the product, not having to incur distribution costs and employment costs associated with distribution and dispensing, and ensuring that a wide range of products is available.

Quality: products are assessed once only against strict criteria of appropriateness, safety, quality, efficacy and cost.

Centralised system operated locally: through operating a central system of control, service and availability can be controlled simply with low costs of administration and the provision of data is facilitated.

Industry is not afraid of change as demonstrated by the recent consultation process and consequent acceptance of new arrangements following extensive consultation. It has also demonstrated that it can work with the NHS on cost savings by maintaining the quality of delivery and service despite four years without a price increase and the absorption of a 2% price reduction in stoma and urology for example.

We contend that the current system, modified as a result of extensive consultation, with the reforms coming into place in April 2010, offers the best value for money to the NHS and that it offers more control through transparent pricing and the use of quality standards.

Relevance of the Part IX Drug Tariff Supply Route to the QIPP Agenda

In August 2009 David Nicholson launched the QIPP agenda in the NHS.

In brief the Industry Drug Tariff Committee believes that the current system for providing medical devices through Part IX of the Drug Tariff and FP10 meets three of the four elements specifically and one in general terms.

"1. Being clear about what actions need to be taken and whether some of those actions need to be organised at larger scaleit seems likely that some of the programmes of action necessary need to be organised at a scale above local health systems to avoid unnecessary reinvention and make the best use of scarce implementation resources. In other words, what are the things we need to do 10 or 152 times?....."

The Drug Tariff is a perfect example of a system that does not need to be reinvented locally. It is important to note the Part IX has just completed a four year consultation process involving seven separate consultations involving all the stakeholders. The results of these consultations are due to be implemented in April 2010.

"2. Getting the right leadership focus and behaviours to address this challenge at every level of the system....."

The Industry believes in this element generally, but cannot demonstrate that there is anything specific relating to the Drug Tariff.

"3. Engaging properly with staff, partners and the public in this challenge...."

The current system which has been heavily modified as a result of 4 years and seven separate consultations is being introduced in April 2010. Engagement has taken place widely with NHS staff, clinicians, patient groups and industry.

"4. Being clear about what changes you think are necessary to the national policy framework to support your workpeople are already considering issues such as how tariffs and other payment methods could better support and incentivise new service models that enhance quality and productivity....."

Once again the extensive consultations have established that a tariff is the best way to meet the objectives of quality, choice, equality of treatment and value for money as laid out in the consultation documents.

We believe that there are many benefits from using a centralised system for delivering essential medical devices in a way designed to meet the NHS objectives, particularly in the areas of quality and value for money. In reaching our conclusions we have considered a number of proposed tenders which are designed to circumnavigate the Drug Tariff system.

Relevance of the Part IX Drug Tariff Supply Route to the current Government's reforms

The Drug Tariff also helps meet many of the objectives for the NHS which the current Government have set out since coming to power in 2010.

• In their original White Paper, *Equity and Excellence: Liberating the NHS*, the Department of Health stated that their ambition was to "achieve healthcare outcomes that are among the best in the world. This can only be realised by involving patients fully in their own care, with decisions made in partnership with clinicians, rather than by clinicians alone".

The document said that "shared decision making should become the norm", and noted that there was international evidence that involving patients in their care improved health outcomes and could reduce costs.

The Drug Tariff Committee believes that the maintenance of the Drug Tariff supports these goals by ensuring that patients are able to choose from a consistent range of products. The current system allows room for niche and specialist products as well as products which may be more commonly used, something which would not happen if local competition was used more widely. By allowing a wide number of companies to operate within the market, the Drug Tariff also promotes the provision to patients of support and advice about the use of products – allowing better patient outcomes and more cost effective use of products.

 NHS England's innovation strategy Innovation, Health and Wealth, was published in December 2011 with the aim of improving the adoption and diffusion of innovation within the NHS. It explicitly states that "silo budgeting can often be a barrier to the adoption and spread of innovation, especially where the cost and savings fall to different budget holders".

The document also states that "local formulary processes should not seek to duplicate NICE assessments or challenge an appraisal recommendation and must never act as a barrier to the uptake of NICE approved medicines. Rather, they should be seen as supporting timely and planned implementation of NICE Technology Appraisals".

Silo budgeting has been a significant contributory factor where the Drug Tariff has been undermined in favour of local arrangements – as procurement officials do not consider the health and economic impacts of restricting patient choice and often lack knowledge of the differences between products.

The Industry Drug Tariff Committee also agrees with the concept that products should be available to all and that decisions on availability should be taken centrally. The list of appliances is currently at the sole discretion of the Secretary of State for Health. While the innovation review promised to review variation where there has been a positive NICE appraisal, we would note that products undergo an assessment of their quality, safety and cost effectiveness in order to be included on the Drug Tariff, and there is no reason why this should be repeated at a local level.

Conclusion

The Industry Drug Tariff Committee believes that after a series of seven consultations over a four year period, patients and the public have clearly stated what they want in terms of the supply of appliances in a community setting.

The value of products and services supplied through the Drug Tariff is almost £1 billion. This represents only a small proportion of total NHS spend. In order that a uniform quality service is provided (regardless of postcode), a centralised system is essential for this niche area of healthcare. The current system which is a centralised system operated locally offers all the benefits of central control together with local ownership of product usage. Any moves which set out to destabilise a well-established supply chain should be approached with extreme caution

In conclusion the Industry Drug tariff Committee is all in favour of change where change is necessary. The NHS will need to focus on the efficient use of labour and cash. The current system minimises the use of labour employed by the NHS while ensuring that product and service is not paid for until after it has been used by the patient. Change should only be considered if it is in the long term interest of patients.

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