Department of Health

Consultation Document

Arrangements for the reimbursement pricing of stoma and incontinence appliances under Part IX of the Drug Tariff

Partial Regulatory Impact Assessment

This document is contained as an annex of the main consultation document

Published date: 23 November 2006

Annex A Partial Regulatory Impact Assessment (RIA)

A.1. TITLE OF PROPOSAL

A.1.1. Arrangements for the reimbursement pricing of stoma and incontinence appliances under Part IX of the Drug Tariff.

A.2. PURPOSE AND INTENDED EFFECT

Objectives

A.2.1. The Department of Health (the Department) is consulting on changes to the arrangements for the items related to stoma and incontinence appliances. The objectives are to:

- Maintain, and where applicable improve, the current quality of care to patients;
- Secure value for money for the NHS;
- Ensure equitable payment for equivalent services and transparent reimbursement pricing;
- Work in partnership to deliver fair prices for the NHS and reasonable returns for suppliers and contractors;
- Facilitate the introduction of innovative solutions;
- Maintain local choice in the provision of services; and
- Keep administration arrangements to the necessary minimum.

A.2.2. The Department proposes to make reductions to the Drug Tariff reimbursement prices for stoma and incontinence appliances with effect from June 2007.

Background

A.2.3. The NHS spends in excess of £631m per annum on items and services for dressings, incontinence appliances, stoma appliances, chemical reagents and other appliances in primary and secondary care. Spend in primary care for stoma and incontinence appliances represents [1]£169 m per annum.

A.2.4. There are in 8,400 different items from 209 different suppliers in these five main groups covering a broad range, from new and innovative items to older commodity-like items. For stoma and incontinence appliances there are 5,800 different items from 68 different suppliers.

A.2.5. In primary care, these items and services are typically dispensed to patients with a prescription by appliance contractors and pharmacy contractors. Occasionally, these items are dispensed by dispensing doctors or personally administered by doctors. Patients may also receive items through the post or from specialist nurses treating them.

A.2.6. The payment system for items and services has been unchanged for almost 20 years.

[1] *Net Ingredient Cost (NIC) prior to deductions, but before appliance contractor uplifts and other adjustments.*

A.2.7. Payments are made to contractors by the Prescription Pricing Authority based on an item's reimbursement price in the Drug Tariff. In summary:

- Pharmacy contractors are paid the Tariff amount less a discount clawback (typically around 10%). The clawback depends on the total number of prescriptions dispensed and is relates to the discount available to the pharmacy contractor from the suppliers. Further allowances and adjustments are made in certain cases.
- Appliance contractors are not subject to the discount clawback. They are paid an uplift of 16-25% on [2]Net Ingredient Cost, to cover funding of services such as home delivery. As a consequence of these payment structures, appliance contractors are generally paid more than pharmacy contractors for dispensing the same item. Further allowances / adjustments are made in certain cases. For services, the fees paid to appliance contractors were estimated to be £28m in 2004.

A.2.8. In October 2005, the Department published a consultation paper, "Arrangements for the Provision of Dressings, Incontinence Appliances, Chemical Reagents and Other Appliances to Primary and Secondary Care". This consultation sought comments on options that the Department considered for changes to arrangements for the provision of dressings, incontinence appliances, stoma appliances, chemical reagents and other appliances to primary and secondary care.

A.2.9. In July 2006, the Department published a subsequent consultation paper titled, "Arrangements for the provision of stoma and incontinence appliances and related support services to patients under Part IX of the Drug Tariff". This included detailed proposals for changes to service specifications and standards and a proposed enhanced classification structure for stoma and incontinence appliances[3].

A.2.10. The Department received a number of responses to the July 2006 consultation, from a cross-section of both the public and industry that were used to inform the proposals contained within this consultation. A summary has been published on:

www.dh.gov.uk/consultations/responsestoconsultations/fs/en

A.2.11. The new Drug Tariff reimbursement prices for some dressings and chemical reagents came into effect on 1 October 2006.

A.3. RATIONALE FOR GOVERNMENT INTERVENTION

A.3.1. There are no EU directives which necessitate this consultation.

A.3.2. If there is no Government intervention in this area then the NHS would not receive best value-for-money on these products in primary care.

A.4. CONSULTATION

Within Government

[2] *Net Ingredient Cost refers to the cost of drugs before discount and does not include any dispensing costs or fees*

[3] *Incontinence products include catheter appliances contained within Part IX*

A.4.1. In preparing this document, the Department has consulted with the Prescription Pricing Division of the Business Services Agency. Where appropriate, legal advice has been sought.

Public Consultation

A.4.2. As indicated in A2.8 and A2.9 earlier consultations, relating to the subject of this consultation, were held according to Cabinet Office guidelines.

A.4.3. There are other related consultation exercises running alongside this consultation.

- Arrangements for the remuneration of services relating to appliances within Part IX of the Drug Tariff.
- Adjustments to the regulatory Terms of Service of Pharmacy and Appliance Contractors within the Pharmaceutical regulations to items in Part IX of the Drug Tariff.

A.4.4. The Department has identified all key stakeholders and a full list is contained within the consultation document. Appropriate mechanisms have been set up for these stakeholders to respond. In addition, the Department will notify key stakeholders directly that the consultation is taking place. Where appropriate, meetings for the purpose of clarification will be held.

A.5. OPTIONS

Summary of Options

A.5.1. The Department considered the following options to set reimbursement prices for stoma and incontinence appliances.

- Do nothing (Option 1);
- Set reimbursement prices in primary care in line with tendered agreements in secondary care (Option 2);
- Set reimbursement prices based on a classification of products and an approach recognised by competition authorities (Option 3).

Option 1: Do nothing

A.5.2. The impact of the do nothing options is shown in paragraph A.3.2.

Option 2: Set reimbursement prices in primary care in line with tendered agreements in secondary care

A.5.3. For some items, such as Dressings and Chemical Reagents within Part IX of the Drug Tariff, comparisons between the reimbursement prices in Primary Care and the tendered agreements within secondary care have been used to set these prices.

A.5.4. The risk of using this option is that many of these products are supplied free of charge to secondary care. This is particularly true in stoma care.

Option 3: Set reimbursement prices based on a classification of products and an approach recognised by competition authorities.

A.5.5. The Department is proposing the following approach to implementing the new arrangements.

- Stage 1: Product classification based on categorisation consulted upon in July 2006[4].
- Stage 2: The use of a proven and recognised approach to reset item prices which is recognised by competition authorities[5].

Product Classification

A.5.6. The first stage would use the existing section headings in the Drug Tariff for stoma and incontinence appliances to classify products of similar medical need into subcategories.

A.5.7. The Department has consulted with healthcare professionals, and taken into account responses from previous consultations, to develop the classification of products further. These healthcare professionals are appropriately qualified in their respective fields and are currently practising in stoma and continence care.

A.5.8. Each proposed subcategory of products lists items having a similar function, size, type of material and type of product features. The allocation of products to specific subcategories is shown, together with relevant prices, in the Annexes of the consultation paper.

Reimbursement Price

A.5.9. Having allocated items to the subcategories, the Department applied an approach to item price setting which is recognised by competition authorities and defines an acceptable range of prices within groups of similar products.

A.5.10. The Department proposes to apply this approach to the products covered in this consultation and adopt the following approach;

- Within each subcategory, products with very low sales which may not represent a valid benchmark for pricing comparisons are excluded.
- Having excluded products with very low sales, in this case less than 0.1%, the lowest priced product of the remaining products becomes the benchmark price.
- A factor is then applied to the benchmark price to give the upper limit for an acceptable range of prices for that subcategory. The Department proposes that a factor of 20% is applied.

A.5.11. Once this approach has been applied to subcategory pricing, it is proposed that the reimbursement prices above the upper limit shall be reduced to the limit whilst those below the limit remain unchanged, including those below the benchmark.

Risks

A.5.12. The introduction of new reimbursement prices may result in some products being withdrawn from the market. If wholesalers cannot continue to offer the same level of discounts to contractors then contractors may not buy products for dispensing. In order to mitigate this risk, at least one product in each subcategory shall be available as a substitute.

Implementation and Delivery

4 *"Arrangements for the provision of stoma and incontinence appliances and related support services to patients under part IX of the Drugs Tariff".*

5 *Competition Authorities refer to the Office of Fair Trading (OFT) and the UK Competition Commission.*

A.5.13. The classification of products with similar medical need, with associated reimbursement pricing shall be available on the Drug Tariff pending the outcome of this consultation. The implementation of the new reimbursement prices shall be reflected in the relevant BSAPPD systems.

A.6. COSTS AND BENEFITS

Sectors and groups affected

A.6.1. The main groups affected by these proposals are pharmacy and appliance contractors.

A.6.2. The number of reimbursement item prices affected by these proposals is approximately 36% of the total 5800 stoma and incontinence items.

A.6.3. Almost overwhelmingly these products are manufactured by multinational companies. A high proportion of the impact relates to products produced by these companies.

A.6.4. The views of clinicians and patient groups will need to be considered.

A.6.5. There are no identified racial equality impacts.

Costs and benefits

A.6.6. The approach set out would reduce the overall cost of the provision of items in the NHS. The range of ingredient costs in primary care would reflect competitive markets more closely. Furthermore fees for associated services would come closer to their true cost of provision whilst allowing a fair return.

A.6.7. The estimated financial impact of these proposals on contractors is approximately £27million per annum.

A.6.8. The table below details specific numbers of products that impact the total estimated financial impact.

Impact banding	Number of products	% of total number of products	% of total impact
£0 - £999	5,183	89%	0.9%
£1,000 - £49,999	549	9.5%	15.5%
£50,000 - £199,999	48	0.8%	16.5%
£200,000 - £499,999	13	0.2%	14.1%
£500,000 - £999,999	6	0.1%	14%
£1,000,000 - £5,000,000	4	0.07%	39%

A.6.9. The product subcategories for catheters have the greatest affect on the total impact. The manufacturers of catheters, for items in Part IX, are largely global manufacturers.

A.6.10. We will be seeking further information from industry and other interested parties on the potential benefits and cost implications of changes.

A.6.11. There are no identified social, environmental nor rural impacts.

A.7. IMPACT ON SMALL FIRMS

A.7.1. There are two groups of small businesses that are potentially affected by the proposals; suppliers and contractors. By far the largest group of small firms impacted are pharmacy contractors.

A.7.2. We can see from BSAPPD payment data to the pharmacy contractors, that item payments are typically less than 5.3% of their tariff income. They would therefore be a correspondingly smaller part of their total income.

A.7.3. The Department will consult fully with the relevant trade associations and small businesses as part of the public consultation. It was concluded that it was better to consult openly with all interested parties potentially affected by the proposals at the same time rather than to discuss the proposals just with small businesses. This avoids the potential for misunderstanding and misinformation from businesses not consulted.

A.8. COMPETITION ASSESSMENT

A.8.1. The consultation relates to the provision of stoma products and continence care products to primary care.

A.8.2. In primary care, manufacturers supply items to contractors either directly or through wholesalers. Contractors dispense items to patients.

A.8.3. Some manufacturers are vertically integrated which means that such manufacturers also act as contractors in dispensing items to patients.

A.8.4. There is no significant market concentration in the contractor group. Amongst manufacturers, in certain sub-categories such as catheters, there are known suppliers with established market shares.

A.8.5. The results indicated by the use of the competition filter indicate that there is no requirement to undertake a full competition assessment.

A.9. ENFORCEMENT, MONITORING AND SANCTIONS

A.9.1. Systems already exist within the BSAPPD to capture and monitor routine activity in primary care.

A.9.2. Enforcement approaches and sanctions are built into the Regulatory Terms of Service for contractors.

A.9.3. The Department of Health will review the effects of any changes related to the approach set out above. The BSAPPD data will be available to establish the pattern of change. The

current benefits tracking process used in NHS PASA would be used to track primary care benefits.

A.10. CONTACT

A.10.1. Points of clarification or questions on this consultation can be sent to:

primaryandacute.part9@dh.gsi.gov.uk

Posted to:

Part IX Consultation
Department of Health
5th floor
New King's Beam House
22 Upper Ground
London
SE1 9BW