

Department of Health

Consultation

Arrangements for the provision of stoma and incontinence appliances and related support services to patients under Part IX of the Drug Tariff

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1 Executive Summary

- 1.1 Following the 2005 consultation paper “Arrangements for the provision of dressings, incontinence appliances, stoma appliances, chemical reagents and other appliances to primary and secondary care”, the Department of Health is undertaking a series of consultations on proposals to make alterations to the arrangements for some products and related services under Part IX of the Drug Tariff.
- 1.2 This consultation seeks views on:
- proposed service specifications, which are intended to bring a more consistent approach to patient care, and to ensure that minimum standards are met by all contractors;
 - a proposed enhanced classification structure for stoma and incontinence appliances, and catheters under Part IX of the Drug Tariff. This enhanced classification structure is intended to facilitate comparison of products for pricing and prescribing purposes.

2 Introduction

- 2.1 In 2005 the Department published a consultation paper “Arrangements for the provision of dressings, incontinence appliances, stoma appliances, chemical reagents and other appliances to primary and secondary care”. We received a substantial number of responses from a wide cross-section of both the public and industry. A summary of this consultation is available at the following address: www.dh.gov.uk/Consultations/ResponsesToConsultations.
- 2.2 This consultation details proposals for a reconfiguration of the services provided in relation to incontinence and stoma appliances in order to ensure equity, consistency and quality in the provision of those appliances. The price of these services will be addressed in a later consultation, likely towards the end of 2006. The proposed service standards also look to address the current practice of ‘agency arrangements’
- 2.3 This consultation also proposes changes to the listing structure of stoma and incontinence appliances, and catheters in the Drug Tariff. This is being introduced to inform Drug Tariff users which products are functionally equivalent and to allow easier comparison of prices.
- 2.4 As indicated, this consultation opens on 27 July and closes on 11 September 2006. We believe that a shorter consultation period is warranted, as most interested parties have been closely involved with this issue since the 2005 consultation paper, which was open for 90 days.
- 2.5 Having completed this work, we intend to consult on the suitability of the Drug Tariff reimbursement prices for these products towards the end of 2006, to ensure that the NHS is receiving value-for-money.

3 Services Provided by Contractors

- 3.1 As the NHS rises to the challenges laid out for it in the white paper “Our health, our care, our say”, all NHS service providers should reconsider how they play their part in the provision of healthcare.
- 3.2 With this in mind, the Department feels it appropriate to review the current provision of services in primary care by contractors to patients with incontinence and stoma needs.
- 3.3 Pharmacies, dispensing doctors and appliance contractors dispense NHS primary care prescriptions in accordance with the Pharmaceutical Service Regulations¹, which includes the contractors’ terms of service. The terms of service requirements are different for pharmacy contractors, dispensing doctors and appliance contractors. The terms of service set out the basic elements of service provision, however many contractors provide a range of other services which do not form part of their terms of service.
- 3.4 Although some industry-wide, voluntary service standards have been agreed through the Patients Industry Professionals (PIPs) Forum, no defined service standards exist, meaning that one patient may receive different services or a different standard of service from another patient.
- 3.5 The Department wishes to ensure equity, consistency and quality in the provision of appliances, and therefore proposes to amend the Pharmaceutical Services Regulations and, in particular, contractors’ terms of service.
- 3.6 To this end, the Department proposes two levels of service, ‘essential services’ to be provided by all contractors, and ‘additional services’ which contractors may choose to provide. All services, both ‘essential’ and ‘additional’ will be provided within a clinical governance framework.
- 3.7 The ‘essential services’ will include dispensing, repeat dispensing, provision of complimentary supplies, product delivery and a telephone care line.
- 3.8 ‘Additional services’ will include product customisation and home visits.
- 3.9 Further details of the proposed services are detailed in Annex A. We are aware that there are a number of other services provided to a comparatively small percentage of the patient population, such as an emergency holiday delivery service. We consider these types of services to be ‘differentiators’, intended to encourage customer loyalty to a particular contractor. We do not propose to include these services in contractors’ terms of service.
- 3.10 The proposed service specifications detailed in Annex A are not intended to address wider services offered to the patient population at large, such as the sponsorship of nursing posts, the running of patient clinics etc. These services do not fall under the provision of Pharmaceutical Services Regulations and may be considered separately later.
- 3.11 This consultation seeks your views on the structure of the proposed services, and to which types of contractors these changes should apply.

¹ *National Health Service (Pharmaceutical Services) Regulations 2005, S.I. 2005/641 (as amended)*

4 Product Classification

- 4.1 Following the 2005 consultation “Arrangements for the provision of dressings, incontinence appliances, stoma appliances, chemical reagents and other appliances to primary and secondary care”, the Department has carried out further analysis of pricing for stoma and incontinence appliances in Part IX of the Drug Tariff.
- 4.2 In order to facilitate this analysis, the Department has developed an enhanced classification system, which will allow functionally equivalent products² to be grouped together into distinct sub-categories. The intention is to use this classification system to compare the prices of functionally equivalent products. This classification system will also help prescribers to identify functionally equivalent products within the vast range of products available in Part IX of the Drug Tariff.
- 4.3 Using the existing Chapter and Section headings used in Prescription Cost Analysis (PCA) data for catheters, incontinence and stoma appliances, new sub-categories have been created one level below this, to define each group of functionally equivalent products currently available on the Drug Tariff. These new sub-categories have been developed by healthcare professionals with extensive clinical experience of the products.
- 4.4 At this stage, we are consulting only on the suitability of the proposed sub-categories. If the Department chooses to take forward this enhanced classification structure following consultation, the allocation of functionally equivalent products to sub-categories, and the re-setting of products prices on that basis, will form part of a further consultation later in 2006.
- 4.5 The Department does not intend to use the introduction of functionally equivalent groupings to reduce the level of patient choice.

5 How To Respond

5.1 The Department seeks your views on the following questions:

5.2 **Service Specifications**

1. What is your view on the proposed service specifications – ‘essential’ and ‘additional’?
2. Are there any other services that should be included?
3. Should any of the services that are listed be removed?

² Functionally equivalent products are defined as having the same practical function, as well as being of similar size, material, format and complexity

4. Are the services that are listed included in the appropriate place i.e. 'essential' or 'additional' services?
5. Should these proposed services and changes to terms of service apply to appliance contractors, pharmacy contractors and dispensing doctors when supplying appliances, or only to appliance contractors?
6. If these proposals should also apply to pharmacy contractors and dispensing doctors, should provision of services under the revised terms of services be mandatory, or should pharmacy contractors and dispensing doctors be able to choose to continue to provide them under their current terms of service?
7. What level of training and experience should contractors carrying out home visits possess?
8. Are clinical governance aspects covered to the appropriate level of detail i.e. are they too thorough or not thorough enough?

5.3 **Product Classification**

9. We intend to introduce the new sub-categories detailed in this document into the Drug Tariff. What is your view on the suitability of the sub-categories proposed for grouping together functionally equivalent products?
10. Are there any sub-categories that should be added to this list?
11. Should any of the sub-categories be broken down further i.e. are these descriptions not detailed enough to define a group of functionally equivalent products ?
12. Is it possible to merge any of the sub-categories together to create broader sub-categories of functionally equivalent products?

5.4 All responses to this consultation must reach the Department by 5pm on Monday, 11 September 2006

5.5 All responses should be sent to:

Primaryandacute.part9@dh.gsi.gov.uk

or posted to:

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

5.6 No related consultation exercises are running alongside this consultation.

5.7 Responses to this consultation will help inform and shape the Department's policy in relation to the development of services, and the structure and classification of products in Part IX of the Drug Tariff.

5.8 The Department intends to publish a summary of responses to this consultation as soon as is practical, and in any case within three months of the closing date of this consultation. This summary will be available on the Department's website at the following address:

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

- 5.9 Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).
- 5.10 If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information that you have provided to be confidential. If we receive a request for disclosure of the information we will take full account of your request, but we cannot give an assurance that confidentiality can be maintained. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.
- 5.11 The Department will process your personal data in accordance with the DPA and, in the majority of circumstances, this will mean that your personal data will not be disclosed to third parties.
- 5.12 The Department is consulting with a wide range of interested parties. A full list of those organisations that have been invited to respond can be found in Annex E. However, the Department welcomes comment from any interested parties.
- 5.13 We believe that a shorter consultation period is warranted, as many interested parties have been closely involved with this issue since the 2005 consultation paper, which was open for 90 days.
- 5.14 The Department also intends to consult further on the issues contained in this consultation document later in 2006.
- 5.15 The Cabinet Office Code of Practice on Consultation details six consultation criteria. These are detailed below:
1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
 2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
 3. Ensure that your consultation is clear, concise and widely accessible.
 4. Give feedback regarding the responses received and how the consultation process influenced the policy.
 5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.
 6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment, if appropriate.

5.16 The consultation is being conducted in accordance with these criteria.

5.17 You are invited to comment on the extent to which these criteria have been adhered to, and to suggest ways for improving the consultation process. Comments or complaints about the consultation process should be directed to:

Consultations Co-ordinator
Department of Health
Skipton House
80 London Road
London
SE1 6LH

Annex A Service Specifications

Clinical Governance

- A.1 All services, whether 'essential' or 'additional', must be provided within a clinical governance framework. This is to ensure that service provision is of the highest possible standard, and so that the contractor can consider where service improvements need to be developed.
- A.2 The framework must include:
- A.3 Patient and public health involvement
- producing a practice leaflet and making it available in an approved manner
 - publicising the NHS services available from the contractor
 - undertaking an approved patient satisfaction survey
 - monitoring arrangements for appliances owed to patients, but which are out of stock
 - having an approved complaints system
 - co-operating with local Patient's Forum visits and taking appropriate action
 - co-operating with inspections by the Primary Care Trust or other relevant statutory authority
 - monitoring compliance with the Disability Discrimination Act 1995
- A.4 Audit
- carrying out 2 audits per year
- A.5 Risk management
- ensuring all stock is procured and handled appropriately
 - ensuring all equipment used is maintained appropriately
 - having an approved incident reporting system, together with arrangements for analysing and responding to critical incidents
 - having suitable standard operating procedures in place
 - having appropriate waste disposal arrangements
 - having a clinical governance lead
 - having child protection procedures
 - monitoring compliance with the Health and Safety at Work etc. Act 1974
- A.6 Clinical effectiveness
- including arrangements for ensuring that appropriate advice is given by the staff via the telephone care line or on home visits
- A.7 Staffing and staff management
- induction of staff
 - training for all staff appropriate to their role
 - checking qualifications and references for all staff engaged in providing NHS services
 - identifying and supporting the development needs of staff, including continuing professional development
 - addressing poor performance

A.8 Use of information

- appropriate arrangements with regard to both rights of access to information and confidentiality
- compliance with 'Confidentiality: the NHS Code of Practice'
- monitoring compliance with the Data Protection Act 1998
- training staff with regard to compliance with the Data Protection Act 1998 and patient confidentiality

Service Standards – Essential Services

Dispensing

Service Description

A.9 The supply of appliances ordered on NHS prescriptions, and the provision of information and advice, enabling safe and effective use by patients and carers of that appliance, and maintenance of appropriate records by contractors.

Aims and intended service outcomes

A.10 To ensure that patients receive appliances safely, and are able to use them effectively.

Service Outline

A.11 Orders for NHS appliances should be dispensed for patients on demand, with reasonable promptness. An estimate of when the appliance will be ready for the patient should be provided, when asked.

A.12 On receipt, the prescription must be processed on the same working day, wherever possible. The contractor must check ordering details (codes, amounts, packs) and contact the prescriber should any of the details be incorrect.

A.13 Where the required appliance is not available, patients should be provided with a written note for any appliance which is owed to them by the contractor and informed when the product is expected to be available. A record of products owed should be made in the patient's record.

A.14 Contractors must ensure that records of all appliances dispensed to the patient are maintained, to facilitate continued care of the patient.

A.15 Accurate data should be held for each patient and prescription, covering name, address, telephone number, GP contact details, prescriber details, exemptions, dispensed appliance history, and referring healthcare professional.

A.16 Where deemed appropriate by the contractor, records will be made of interventions, advice given to the patient, and referrals that have been made.

A.17 Appropriate advice should be given to the patient to enable them to utilise the appliance and to meet their personal need for general information on the product.

A.18 Patients should be advised on the safe storage and keeping of appliances.

- A.19 Contractors may refuse to supply any appliances ordered on a prescription in certain circumstances, including where the contractor:
- does not believe the prescription is genuine;
 - thinks there is an error in the prescription or that making the supply would be contrary to their professional judgement; or
 - is subjected to or threatened with violence by the person presenting the prescription.
- A.20 Contractors may not dispense appliances before receiving a valid prescription, except in the dispensing of urgent supplies. In this exceptional circumstance, urgent supplies of appliances may be dispensed by the contractor before receiving the prescription, at the request of the prescriber, so long as the prescriber undertakes to provide the prescription within 72 hours. Prescribers must not be contacted by contractors to provide retrospective prescriptions.
- A.21 The contractor must ensure that the patient's signature is captured, or that of their representative, to indicate either their exemption status or the number of charges paid.
- A.22 If a patient or their representative has declared exemption from charges, the contractor must explicitly indicate if they have not seen evidence to support this.
- A.23 The contractor must alert the patient's healthcare professional of any unusual patient requests or any change to the ordering pattern.
- A.24 Similarly, if any problems or queries arise in the dispensing of the appliance, the patient's healthcare professional should be contacted.
- A.25 The patient should not be offered an alternative, or newer, appliance than that one that has been prescribed for them. If the contractor feels that there may be a better appliance available for that individual patient, then this should be discussed with the patient's prescriber.
- A.26 Where a patient gives a prescription to a contractor who cannot fully fill that prescription, that contractor may pass it to an alternative contractor, in consultation with the patient, but must not receive any payment for this prescription from the alternative contractor.
- A.27 Contractors must not contact patients to remind them to order appliances, unless directed by the patient's healthcare professional.
- A.28 In time, contractors will be expected to be able to access and operate the electronic prescription service and to dispense electronic prescriptions.

Repeat Dispensing

Service Description

A.29 The management and dispensing of repeatable NHS prescriptions for appliances, in partnership with the patient and the prescriber.

Aims and intended service outcomes

A.30 To increase patient choice and convenience, by allowing them to obtain their regular prescription appliances directly from an appliance contractor for a period agreed by the prescriber.

A.31 To minimise wastage by reducing the number of dispensed appliances which are not required by the patient.

A.32 To reduce the workload of general medical practices, by lowering the burden of managing repeat prescriptions.

Service outline

A.33 The contractor should inform patients about repeat dispensing arrangements, including the importance of only requesting those products which are actually required by the patient. This is to reduce hoarding and waste.

A.34 The contractor should securely store a patient's repeatable prescription, and also the related batch issues, if requested by the patient.

A.35 The contractor should dispense in accordance with the directions given on the repeatable prescription. If no specific instructions are given by the prescriber, the contractor should use his professional judgment to decide when it is appropriate for the products to be dispensed.

A.36 An NHS repeatable prescription needs to be dispensed for the first time within six months of being written and can then only be dispensed subsequently for up to a year from being written, or until any expiry date specified by the prescriber, whichever is less.

A.37 Prior to each dispensing episode, the contractor should ensure that the patient is using, and is likely to continue to use, the appliances appropriately, and the patient does not indicate any difficulties which may suggest the need for a review of the appliance.

A.38 The contractor should also check if the patient's appliances have been altered since the prescriber authorised the repeatable prescription. They should also check if there have been any other changes in the patient's condition or situation since that time, which may indicate that the appliances need to be reviewed by the prescriber.

- A.39 After each dispensing episode, an appropriate batch issue should be endorsed in accordance with Drug Tariff requirements and forwarded to the NHS Business Services Authority Prescription Pricing Division (NHS BSA PPD).
- A.40 If a contractor is concerned about the appropriateness of dispensing a batch issue, due to a change in the patient's condition or requirements, he may refuse to dispense the product. The contractor should advise the patient to seek an appointment with the prescriber and/or may contact the prescriber to alert him to the concern.
- A.41 The contractor should maintain records of the dispensing of repeatable prescriptions, so that there is a clear audit trail in place. This should allow staff to unambiguously determine dates and quantities of appliances supplied during each dispensing episode. Records of interventions made, and considered by the contractor to be significant, should be maintained in the patient's record.
- A.42 The contractor should inform the prescriber of any issues which occur in relation to the repeatable prescription, and which are deemed to be significant. The patient should not be offered an alternative, or newer, appliance than the one that has been prescribed for them. If the contractor feels that there may be a better appliance available for that individual patient, then this should be discussed with the patient's healthcare professional
- A.43 The contractor should undertake appropriate training, relating to the operational management of repeat dispensing, before providing this service.

Provision of Complimentary Supplies

Service Description

A.44 Providing the patient with complimentary supplies.

Aims and intended service outcomes

A.45 Providing auxiliary supplies to the patient to facilitate good use of the dispensed appliance.

Service outline

A.46 Where appropriate, a complimentary supply of wipes and disposal bags must be provided by the contractor with the first delivery to the patient.

A.47 Thereafter, they should be supplied free of charge when requested by the patient.

A.48 If appropriate, a free night bag stand must be provided by the contractor with the first delivery to the patient.

A.49 The quantity supplied should be appropriate to the use of the appliance, and the volume of appliances dispensed.

A.50 No other complimentary appliances or samples should be given to the patient without first consulting with the patient's healthcare professional.

Delivery

Service Description

A.51 Delivery of the dispensed appliance to the patient.

Aims and intended outcomes

A.52 To increase patient convenience by allowing patients to have the prescription delivered.

Service Outline

A.53 Delivery must be made to the patient within 2 working days of the contractor receiving the prescription.

A.54 The delivery company should provide the patient with an accurate delivery date, and if possible, a delivery time.

A.55 Where delivery is made by an employee of the contractor, it should be understood that this does not constitute a 'home visit', as detailed below.

A.56 The delivery should be in a plain package, with no distinguishing features that could indicate its contents. Similarly, if the contractor chooses to use a courier delivery service, the vehicle or the delivery person's uniform should give no indication of the type of delivery being made.

A.57 The package should contain clear instructions for alternative delivery options.

Telephone Care Line

Service Description

A.58 A telephone care line to provide information and advice to patients.

Aims and intended outcomes

A.59 To allow the patient to contact the contractor, to receive advice and information about their dispensed appliance.

A.60 The care line is intended specifically to assist patients with concerns or questions relating to the use of their dispensed appliance.

Service description

A.61 The contractor must provide access for patients to a telephone care line, staffed by suitably trained and experienced people, as detailed below. The care line must be available between the hours of 9am to 5pm as a minimum, Monday to Friday.

A.62 Out of hours messages should provide contact details of NHS Direct.

A.63 This care line must be distinct from any telephone ordering service that the contractor may offer.

A.64 Where a problem cannot be resolved through the care line, the contractor must refer the patient to their healthcare professional, or if appropriate, carry out a home visit. If the contractor does not offer home visits they must seek the patient's permission to refer them to another contractor to carry this out.

A.65 Those staffing the telephone care line should have, as a minimum:

- Knowledge of all of the relevant appliances available on Part IX of the Drug Tariff
- Knowledge of how to remove or change appliances
- Knowledge of how to dispose of used appliances
- Specific knowledge on the usage of all 1 and 2 piece stoma systems, pouches, closures and clips
- Knowledge of the preparation and correct positioning of a new appliance
- Knowledge of how to clean the stoma and peristomal skin
- Knowledge of the linkage of leg bag drainage system to night drainage system
- Knowledge of continence related issues such as:
 - Intermittent self-catheterisation
 - Indwelling catheters (urethra and suprapubic)
 - Sheath systems
 - Drainage
 - Collection devices including pants and pads
- Knowledge of when to refer the patient to their healthcare professional

Service Standards – Additional Services

Appliance Customisation

Service Description

A.66 Where needed, the contractor will customise the dispensed appliance for the patient.

Aims and intended outcomes

A.67 Patients who are unable to customise their own appliances can have this carried out for them by the contractor, ensuring optimal performance of the dispensed appliance.

Service Description

A.68 If requested by the patient or the patient's healthcare professional, the contractor will customise the appliance. This may include cutting, or attaching any wafers, flanges, filters or clips to the appliance prior to delivery.

A.69 The contractor will maintain a record of the template needed for that patient, and will cut the appliance to shape prior to delivery.

Home Visits

Service Description

A.70 A visit is made to the patient's home, or place of residence, by the contractor.

Aims and intended outcomes

A.71 To resolve any issues or difficulties face-to-face that cannot be dealt with via the telephone care line.

A.72 To provide face-to face-support and information for patients using appliances for the first time, or to those patients using new appliances.

A.73 To measure and fit any new appliances.

Service Outline

A.74 In general, visits should be made at the request of a patient, their representative or their healthcare professional, if difficulty is being experienced in using their appliance. However contractors may also identify when patient would benefit from a home visit, in particular:

- When a patient is discharged from secondary care for the first time, or when a patient receives a new appliance
- When measuring for a customisation template
- When a query on the telephone care line cannot be dealt with over the phone

A.75 A suitably trained and experienced person will visit the patient. A visit is distinct from any home visit provided by an NHS employee, and must be provided by an employee or representative of the contractor.

A.76 The suitably trained and experienced person must spend at least 20 minutes in the patient's home to qualify as a home visit.

A.77 Where specifically requested by the patient, the home visit must take place within 2 working days of the request being made.

A.78 Visits might include measurement of the patient's stoma so that a template may be made, girdle measuring and fitting, assessment and fitting of sheath systems and teaching patients to self-catheterise.

A.79 The contractor must keep records of visits, including who made the visits, where they were carried out, who else was present e.g. carer, and any interventions and advice.

A.80 A contractor who does not provide 'additional services' may refer a patient to a contractor who does, where they think a home visit is required. After seeking patient permission, the provider of

the home visit would need to provide the referring contractor with details and outcomes of the home visit (for example templates for customisation).

Annex B Proposed Classification of Incontinence Appliances

Current PCA Section

Proposed new sub-category
Proposed new sub-category
Proposed new sub-category
Proposed new sub-category

Anal Plugs

Anal plug, porous, semi absorbent foam, small
Anal plug, porous, semi absorbent foam, large

Catheter Valves

Catheter valve with lever or push-pull tap, latex, various sizes
Catheter valve with lever or push-pull tap, non-latex, various sizes

Drainable Dribbling Appliances

Drainable Dribbling Appliances, various sizes

Faecal Collectors

Faecal collector pouch with foam backed skin barrier, 500ml
Faecal collector pouch with foam backed skin barrier, 1000ml

Incontinence Sheaths

Sheath incontinence one piece system self adhesive latex
Sheath incontinence one-piece system self adhesive non-latex
Sheath incontinence one-piece system self adhesive silicone clear
Sheath incontinence one-piece system self adhesive transparent synthetic polymer latex free
Sheath incontinence one-piece system short sheath non-latex
Sheath incontinence one-piece system short sheath self adhesive silicone clear
Sheath incontinence one-piece system with wider adhesive band clear silicone
Sheath incontinence two-piece system with hydrocolloid liner clear synthetic polymer
Sheath incontinence two-piece system with hydrocolloid liner non-latex

Incontinence Sheath Fixing Strips & Adhesives

Adhesive strips, various sizes
Holders, various sizes
Straps, various sizes
Tape 5m, various sizes

Leg Bags

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, t-tap (push-pull), sample port and Velcro

fasteners, 350ml

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, t-tap (push-pull), sample port and Velcro fasteners, 500ml

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, t-tap (push-pull), sample port and Velcro fasteners, 750ml

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, t- tap (push-pull), sample port, fabric backing and Velcro fasteners, 350ml

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, t- tap (push-pull), sample port, fabric backing and Velcro fasteners, 500ml

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, t- tap (push-pull), sample port, fabric backing and Velcro fasteners, 750ml

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, lever tap, sample port and Velcro fasteners, 350ml

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, lever tap, sample port and Velcro fasteners, 500ml

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, lever tap, sample port and with Velcro fasteners, 750ml

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, lever tap, sample port, fabric backing and Velcro fasteners, 350ml

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, lever tap, sample port, fabric backing and Velcro fasteners, 500ml

Urine drainage leg bag sterile with short, medium, long or adjustable inlet tubing, lever tap, sample port, fabric backing and Velcro fasteners, 750ml

Urine drainage paediatric leg bag sterile with short inlet tubing, lever tap, sample port and with Velcro fasteners, 120ml

Non-sterile urine drainage leg bag with short or medium inlet tubing, lever tap and Velcro fasteners, 350ml

Non-sterile urine drainage leg bag with short or medium inlet tubing, lever tap and Velcro fasteners, 500ml
Urine drainage knee bag sterile with short, medium, long or adjustable inlet tubing, t-tap (push-pull), sample port, fabric backing and Velcro fasteners, 1300ml

Urine drainage knee bag sterile with short, medium, long or adjustable inlet tubing, lever tap, sample port, fabric backing and Velcro fasteners, 400ml

Urine drainage knee bag sterile with short, medium, long or adjustable inlet tubing, lever tap, sample port, fabric backing and Velcro fasteners, 700ml

Urine drainage knee bag sterile with short, medium, long or adjustable inlet tubing, lever tap, sample port, fabric backing and Velcro fasteners, 1300ml

Urine drainage knee bag sterile with short, medium, long or adjustable inlet tubing, t-tap (push-pull), sample port, fabric backing and Velcro fasteners, 400ml

Urine drainage knee bag sterile with short, medium, long or adjustable inlet tubing, t-tap (push-pull), sample port, fabric backing and Velcro fasteners, 700ml

Urine "belly" bag, high capacity bag for 2-3 weeks usage, standard

Night Drainage Bags

Urine drainage bag non-sterile non-drainable with narrow bore tubing, inlet connector, 2 litres

Urine drainage bag non-sterile non-drainable with narrow bore tubing, inlet connector and sample port, 2 litres

Urine drainage bag non-sterile with wide bore tubing, inlet connector and single drain tap, 2 litres

Urine drainage bag sterile with narrow bore tubing, inlet connector, t-tap (push-pull) and sample port 2 litres

Urine drainage bag sterile with wide bore tubing, inlet connector, lever tap and sample port, 2 litres

Urine drainage bag sterile with wide bore tubing, inlet connector, t-tap (push-pull) and sample port, 2 litres

Suspensory Systems

Holster for drainage bag, left or right hand, small
Holster for drainage bag, left or right hand, medium
Holster for drainage bag, left or right hand, large
Holster for drainage bag, left or right hand, extra large
Urine drainage leg bag holder/sleeve, small
Urine drainage leg bag holder/sleeve, medium
Urine drainage leg bag holder/sleeve, large
Urine drainage leg bag holder/sleeve, extra large
Urine drainage leg bag strap, foam/Velcro washable
Urine drainage leg bag strap, latex

Tubing & Accessories

Urine director female
Urine director male
Urine drainage 2 litre bag connector
Urine drainage bag extension tube

Urinal Systems

Pubic pressure urinals
Retracted penis pouch

Annex C Proposed Classification of Stoma Appliances

Current PCA Section

Proposed new sub-category
Proposed new sub-category
Proposed new sub-category
Proposed new sub-category

Adhesive Discs/Rings/ Pads/Plasters

Adhesive pads, hypoallergenic, small (up to 38mm)
Adhesive pads, hypoallergenic, medium (39-70 mm)
Adhesive pads, hypoallergenic, large (71mm and over)
Adhesive pads, non-hypoallergenic, small (up to 38mm)
Adhesive pads, non-hypoallergenic, medium (39-70 mm)
Adhesive pads, non-hypoallergenic, large (over 71mm)
Adhesive rings, double-sided, hypoallergenic, various sizes
Adhesive rings, double-sided, non hypoallergenic, various sizes
Adhesive rings, single-sided, hypoallergenic, various sizes
Adhesive rings, single-sided, non hypoallergenic, various sizes
Adhesive tape, hypoallergenic, various sizes
Adhesive tape, non hypoallergenic, various sizes
Adhesive remover lotion, various sizes
Adhesive remover spray, CFC friendly, various sizes
Adhesive remover wipes, various sizes
Adhesive paste, latex, various sizes
Adhesive paste, non-latex, various sizes
Adhesive spray, latex, various sizes
Adhesive spray, non-latex, various sizes

Bag Closures

Re-usable plastic clip closures, various sizes
Wire closures, various sizes

Bag Covers

Non-woven fabric (paper), small
Non-woven fabric (paper), medium
Non-woven fabric (paper), large
Woven fabric (cotton), small
Woven fabric (cotton), medium
Woven fabric (cotton), large

Belts

Belt and protective shield, small
Belt and protective shield, medium
Belt and protective shield, large
Made-to-measure ostomy girdle, various sizes
Ostomy girdle support belt only, small
Ostomy girdle support belt only, medium
Ostomy girdle support belt only, large
Pouch retaining belt and ring, small
Pouch retaining belt and ring, medium
Pouch retaining belt and ring, large
Pouch retaining belt only (fits with belt lugs on pouch), small
Pouch retaining belt only (fits with belt lugs on pouch), medium
Pouch retaining belt only (fits with belt lugs on pouch), large
Standard ostomy girdle, small
Standard ostomy girdle, medium
Standard ostomy girdle, large

Colostomy Bags

Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, convex, small/mini
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, convex, medium/midi
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, convex, large/maxi
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, flushable, small/mini
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, flushable, medium/midi
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, flushable, large/maxi
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, integral pouch cover, small/mini
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, integral pouch cover, medium/midi
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, integral pouch cover, large/maxi
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, microporous collar, small/mini
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, microporous collar, medium/midi
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, microporous collar, large/maxi
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, no microporous collar, small/mini
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, no microporous collar, medium/midi
Closed bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, no microporous collar, large/maxi
Closed bag, skin-friendly adhesives, odour-proof, microporous collar, small/mini
Closed bag, skin-friendly adhesives, odour-proof, microporous collar, medium/midi
Closed bag, skin-friendly adhesives, odour-proof, microporous collar, large/maxi
Closed bag, skin-friendly adhesives, odour-proof, microporous collar, flatus filters, small/mini
Closed bag, skin-friendly adhesives, odour-proof, microporous collar, flatus filters, medium/midi
Closed bag, skin-friendly adhesives, odour-proof, microporous collar, flatus filters, , large/maxi
Closed bag, skin-friendly adhesives, odour-proof, microporous collar, integral pouch cover, small/mini
Closed bag, skin-friendly adhesives, odour-proof, microporous collar, integral pouch cover, medium/midi
Closed bag, skin-friendly adhesives, odour-proof, microporous collar, integral pouch cover, large/maxi
Closed bag, skin-friendly adhesives, odour-proof, no microporous collar, small/mini
Closed bag, skin-friendly adhesives, odour-proof, no microporous collar, medium/midi
Closed bag, skin-friendly adhesives, odour-proof, no microporous collar, large/maxi

Deodorants

Deodorising drops, various sizes
Deodorising drops with odour neutraliser, various sizes
Deodorising power, various sizes
Deodorising power with odour neutraliser, various sizes
Deodorising spray, various sizes
Deodorising spray with odour neutraliser, various sizes
Deodorising spray with odour neutraliser and lubricant, various sizes

Discharge Solidifying Agents

Discharge solidifying capsules, various sizes
Discharge solidifying sachets, various sizes

Filters/ Bridges

Adhesive, deodorising flatus filters, various sizes
Bridge, wire or foam, various sizes

Flanges

Flanges for older appliances, small (up to 38mm)
Flanges for older appliances, medium (39-70 mm)
Flanges for older appliances, large (71mm and over)

Ileostomy Bags

Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouch backing, convex, integral clip, small/mini
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouch backing, convex, integral clip, medium/midi
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouch backing, convex, integral clip, large/maxi
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouch backing, convex, integral clip with additional fistula/wound management features, small/mini
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouch backing, convex, integral clip with additional fistula/wound management features, medium/midi
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouch backing, convex, integral clip with additional fistula/wound management features, large/maxi
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, convex, no clip, small/mini
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, convex, no clip, medium/midi
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, convex, no clip, large/maxi
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, integral clip, small/mini
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, integral clip, medium/midi
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, integral clip, large/maxi
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, no clip, small/mini
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, no clip, medium/midi
Drainable bag, skin-friendly adhesives, odour-proof, flatus filters, pouchbacking, no clip, large/maxi
Drainable bag, skin-friendly adhesives, odour-proof, microporous collar, small/mini
Drainable bag, skin-friendly adhesives, odour-proof, microporous collar, medium/midi
Drainable bag, skin-friendly adhesives, odour-proof, microporous collar, large/maxi
Drainable bag, skin-friendly adhesives, odour-proof, microporous collar, integral pouch cover, small/mini
Drainable bag, skin-friendly adhesives, odour-proof, microporous collar, integral pouch cover, medium/midi
Drainable bag, skin-friendly adhesives, odour-proof, microporous collar, integral pouch cover, large/maxi

Drainable bag, skin-friendly adhesives, odour-proof, no microporous collar, small/mini
Drainable bag, skin-friendly adhesives, odour-proof, no microporous collar, medium/midi
Drainable bag, skin-friendly adhesives, odour-proof, no microporous collar, large/maxi
Drainable bag, skin-friendly adhesives, odour-proof, no microporous collar, integral pouch cover, small/mini
Drainable bag, skin-friendly adhesives, odour-proof, no microporous collar, integral pouch cover, medium/midi
Drainable bag, skin-friendly adhesives, odour-proof, no microporous collar, integral pouch cover, large/ maxi

Irrigation Washout Appliances

Irrigation washout appliance system (includes pouch, tube and cone), various sizes
Irrigation washout appliance, replacement cone, various sizes
Irrigation washout appliance, replacement pouch, various sizes
Irrigation washout appliance, replacement tube, various sizes

Pressure Plates/ Shields

Convex inserts, various sizes
Protective shield, various sizes
Standard pressure plate, various sizes

Skin Fillers/ Protectives

Aerosol skin protective, various sizes
Cream skin protective, various sizes
Powder skin protective, various sizes
Wipes skin protective, various sizes
Stick applicator skin protective, various sizes
Skin cleanser wipes, various sizes
Liquid skin cleanser, bottle-format, various sizes
Soap skin cleanser, various sizes
Strip skin fillers, various sizes
Paste skin fillers, tube , various sizes

Skin Protectors

Skin protector foam pads, various sizes
Skin protector wafer, hydrocolloid, various sizes
Skin protector wafer, karaya, various sizes
Skin protector washers, hydrocolloid, small
Skin protector washers, hydrocolloid, standard/medium
Skin protector washers, karaya, small
Skin protector washers, karaya, standard/medium

Stoma Caps

Stoma caps, filter, small
Stoma caps, filter, standard/medium
Stoma caps, no filter, small
Stoma caps, no filter, standard/medium

Tubing

Connectors, various sizes

Tubes, various sizes

Two-piece Ostomy Systems

Colostomy pouches for two-piece ostomy systems, closed bag, odour-proof, small/mini

Colostomy pouches for two-piece ostomy systems, closed bag, odour-proof, medium/midi

Colostomy pouches for two-piece ostomy systems, closed bag, odour-proof, large/maxi

Colostomy pouches for two-piece ostomy systems, closed bag, odour-proof, flatus filter, small/mini

Colostomy pouches for two-piece ostomy systems, closed bag, odour-proof, flatus filter, medium/midi

Colostomy pouches for two-piece ostomy systems, closed bag, odour-proof, flatus filter, large/maxi

Colostomy pouches for two-piece ostomy systems, closed bag, odour-proof, flatus filter, integral pouch cover, small/mini

Colostomy pouches for two-piece ostomy systems, closed bag, odour-proof, flatus filter, integral pouch cover, medium/midi

Colostomy pouches for two-piece ostomy systems, closed bag, odour-proof, flatus filter, integral pouch cover, large/maxi

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure coupling device, microporous collar, small (up to 38mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure coupling device, microporous collar, medium (39-70 mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure coupling device, microporous collar, large (71mm and over)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure coupling device, microporous collar, integral convexity, small (up to 38mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure coupling device, microporous collar, integral convexity, medium (39-70 mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure coupling device, microporous collar, integral convexity, large (71mm and over)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure coupling device, no microporous collar, small (up to 38mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure coupling device, no microporous collar, medium (39-70 mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure coupling device, no microporous collar, large (71mm and over)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, micro-porous adhesive, convex, small (up to 38mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, micro-porous adhesive, convex, medium (39-70 mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, micro-porous adhesive, convex, large (71mm and over)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, microporous collar, small (up to 38mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, microporous collar, medium (39-70 mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, microporous collar, large (71mm and over)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, no micro-porous adhesive, convex, small (up to 38mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, no micro-porous adhesive, convex, medium (39-70 mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, no micro-porous adhesive, convex, large (71mm and over)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, no microporous collar, small (up to 38mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, no microporous collar, medium (39-70 mm)

Flanges for two-piece ostomy systems, skin-friendly adhesive, secure second-generation coupling device, no microporous collar, large (71mm and over)

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, flatus filter, pouch backing, integral clip, small/mini

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, flatus filter, pouch backing, integral clip, medium/midi

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, flatus filter, pouch backing, integral clip, large/maxi

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, flatus filter, pouch backing, integral clip with additional fistula/ wound management features, small/mini

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, flatus filter, pouch backing, integral clip with additional fistula/ wound management features, medium/midi

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, flatus filter, pouch backing, integral clip with additional fistula/ wound management features, large/maxi

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, flatus filter, pouch backing, no clip, small/mini

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, flatus filter, pouch backing, no clip, medium/midi

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, flatus filter, pouch backing, no clip, large/maxi

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, no clip, small/mini

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, no clip, medium/midi

Ileostomy pouches for two-piece ostomy systems, drainable pouch, odour-proof, no clip, large/maxi

Urostomy pouches for two-piece ostomy systems, bag with a tap and drip collector, odour-proof, non-return valve, small/mini

Urostomy pouches for two-piece ostomy systems, bag with a tap and drip collector, odour-proof, non-return valve, medium/midi

Urostomy pouches for two-piece ostomy systems, bag with a tap and drip collector, odour-proof, non-return valve, large/maxi

Urostomy pouches for two-piece ostomy systems, bag with a tap, odour-proof, non-return valve, small/mini

Urostomy pouches for two-piece ostomy systems, bag with a tap, odour-proof, non-return valve, medium/midi

Urostomy pouches for two-piece ostomy systems, bag with a tap, odour-proof, non-return valve, large/maxi

Urostomy pouches for two-piece ostomy systems, bag with tap and drip collector, odour-proof, non-return valve and pouch backing, small/mini

Urostomy pouches for two-piece ostomy systems, bag with tap and drip collector, odour-proof, non-return valve and pouch backing, medium/midi

Urostomy pouches for two-piece ostomy systems, bag with tap and drip collector, odour-proof, non-return valve and pouch backing, large/maxi

Urostomy Bags

Bag with tap, skin-friendly adhesives, odour-proof, microporous collar, non-return valve, small/mini

Bag with tap, skin-friendly adhesives, odour-proof, microporous collar, non-return valve, medium/midi

Bag with tap, skin-friendly adhesives, odour-proof, microporous collar, non-return valve, large/maxi

Bag with tap, skin-friendly adhesives, odour-proof, microporous collar, non-return valve, small/mini

Bag with tap, skin-friendly adhesives, odour-proof, microporous collar, non-return valve, medium/midi

Bag with tap, skin-friendly adhesives, odour-proof, microporous collar, non-return valve, large/maxi

Bag with tap, skin-friendly adhesives, odour-proof, no microporous collar, non-return valve, small/mini

Bag with tap, skin-friendly adhesives, odour-proof, no microporous collar, non-return valve, medium/midi

Bag with tap, skin-friendly adhesives, odour-proof, no microporous collar, non-return valve, large/maxi

Bag with tap, skin-friendly adhesives, odour-proof, non-return valve, drip tap pouch backing, convex, small/mini

Bag with tap, skin-friendly adhesives, odour-proof, non-return valve, drip tap pouch backing, convex, medium/midi
Bag with tap, skin-friendly adhesives, odour-proof, non-return valve, drip tap pouch backing, convex, large/maxi
Bag with tap, skin-friendly adhesives, odour-proof, non-return valve, drip tap pouch backing, convex, small/mini
Bag with tap, skin-friendly adhesives, odour-proof, non-return valve, drip tap pouch backing, convex, medium/midi
Bag with tap, skin-friendly adhesives, odour-proof, non-return valve, drip tap pouch backing, convex, large/maxi
Bag with tap, skin-friendly adhesives, odour-proof, non-return valve, drip tap, pouch backing, small/mini
Bag with tap, skin-friendly adhesives, odour-proof, non-return valve, drip tap, pouch backing, medium/midi
Bag with tap, skin-friendly adhesives, odour-proof, non-return valve, drip tap, pouch backing, large/maxi
Drainable, re-usable, rubber urostomy bags, various sizes

Annex D Proposed Classification of Catheters

Current PCA Section

Proposed new sub-category
Proposed new sub-category
Proposed new sub-category
Proposed new sub-category

Intermittent catheter, PVC, non-lubricated, male or female
Intermittent catheter, hydrophilic, male or female
Intermittent catheter, hydrophilic, paediatric
Intermittent catheter, hydrophilic, in sterile water, male or female
Intermittent catheter with urine bag, hydrophilic, in sterile water, male or female
Intermittent catheter, lubricated gel coating, male or female
Intermittent catheter with urine bag, lubricated gel coating, male or female
Intermittent catheter, PVC, urethral Scott, female
Intermittent catheter, PVC, urethral, male or female
Intermittent catheter, urethral, soft rubber, male
Silver, re-usable catheter, female
Stainless steel, re-usable catheter, female
Self-retaining catheter 2-way 10ml balloon short-term silicone elastomer coated latex, male or female
Self-retaining catheter 2-way 30ml balloon short-term silicone elastomer coated latex, male
Self-retaining catheter 2-way 10ml balloon medium term PTFE coated latex, male or female
Self-retaining catheter 2-way 30ml balloon medium term PTFE coated latex, male
Self-retaining catheter 2-way 10ml balloon medium term PTFE coated latex with pre-filled syringe of sterile water, male or female
Self-retaining catheter 2-way 10ml pre-filled balloon medium term PTFE coated latex, male or female
Self-retaining catheter 2-way 10ml balloon long-term silicone, male or female
Self-retaining catheter 2-way 3-5ml balloon long-term silicone, paediatric
Self-retaining catheter 2-way 30ml balloon long-term silicone, male
Self-retaining catheter 2-way 10ml balloon long-term silicone with pre-filled syringe of sterile water, male or female
Self-retaining catheter 2-way 10ml balloon long-term hydrogel, male or female
Self-retaining catheter 2-way 30ml balloon long-term hydrogel male
Self-retaining catheter 2-way 10ml balloon long-term hydrogel with pre-filled syringe of sterile water, male or female
Self-retaining catheter 2-way 10ml pre-filled balloon long-term hydrogel, male or female
Self-retaining catheter 2-way 10ml balloon long-term hydrogel coated silicone, male or female
Self-retaining catheter 2-way 10ml balloon long-term hydrogel coated silicone with pre-filled syringe of sterile water, male or female
Self-retaining 2-way 10ml balloon medium term silver alloy coated hydrogel with pre-filled syringe, male or female
Self-retaining 2-way 10ml balloon medium term silver alloy coated hydrogel, male or female

Annex E List of Consulted Organisations

The consultation paper has been sent to the following organisations:

Stakeholder Group	Organisation
Department of Health and NHS organisations	<ul style="list-style-type: none"> • All Trust Chief Executives • Procurement Board Leads • Collaborative Procurement Organisations • Monitor – Foundation Trusts • NHS Purchasing and Supply Agency • NHS Business Services Authority • Counter Fraud and Security Management Service • Health Industry Taskforce (HITF) • NHS Confederation
Other government bodies	<ul style="list-style-type: none"> • HM Treasury • Department of Trade and Industry (DTI) • Devolved Administrations (Wales, Scotland) • Northern Ireland Office • Office of the Deputy Prime Minister (ODPM) • Office of Fair Trading
Trade associations	<ul style="list-style-type: none"> • British Healthcare Trades Association • Association of British Healthcare Industries • Pharmaceutical Services Negotiating Committee • National Pharmacy Association • British Association of Pharmaceutical Wholesalers • Specialist Independent Appliance Wholesalers
Physician and nursing associations	<ul style="list-style-type: none"> • General Practitioners Committee • Royal College of General Practitioners • Royal College of Nursing • World Council of Enterostomal Therapists • Association of Coloproctology
Patient associations	<ul style="list-style-type: none"> • The Patients Association • Patients Industry Professionals Forum • The Ileostomy and Internal Pouch Support Group • Continence Foundation • Urostomy Association • The Colostomy Association

Annex F Glossary of Terms

Term	Definition
Appliance Contractors	Those providers permitted to dispense appliances under Part IX of the Drug Tariff
Drug Tariff	The Drug Tariff is the list developed and maintained by the Prescription Pricing Division of the NHS Business Services Authority, which details what will be paid to contractors for NHS medicines and appliances. Further information on the Drug Tariff can be found at www.ppa.org.uk/ppa/edt_intro.htm
Part IX	A section of the Drug Tariff which contains, amongst other things, the listings of stoma and incontinence appliances which are permitted to be prescribed.
Pharmacy Contractors	Community pharmacies approved to provide the products contained under Part IX of the Drug Tariff.

Annex G Consultation Response Proforma

The following response proforma can also be found as a separate document on the Department's website at www.dh.gov.uk/liveconsultations.

Respondent Details (Please provide the details of a single point of co-ordination for your response)

Title	Mr / Mrs / Miss / Ms / Dr / Professor / Other
Full Name	
Organisation	
Your Role	
Address (including postcode)	
Email Address	
Phone Contact	

If you are replying on behalf of a group of respondents or a number of organisations, please complete the following information:

Organisations represented within this response	
--	--

Response details

Date of response:	Closing date: TBC
<p>Confidentiality: Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).</p> <p>If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information that you have provided to be confidential. If we receive a request for disclosure of the information we will take full account of your request, but we cannot give an assurance that confidentiality can be maintained. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.</p> <p>The Department will process your personal data in accordance with the DPA and, in the majority of circumstances, this will mean that your personal data will not be disclosed to third parties.</p>	

1. What is your view on the proposed service specifications – ‘essential’ and ‘additional’?

Comments:

2. Are there any other services that should be included?

Comments:

3. Should any of the services that are listed be removed?

Comments:

4. Are the services that are listed included in the appropriate place i.e. ‘essential’ or ‘additional’ services?

Comments:

5. Should these proposed services and changes to terms of service apply to appliance contractors, pharmacy contractors and dispensing doctors when supplying appliances, or only to appliance contractors?

Comments:

6. If these proposals should also apply to pharmacy contractors and dispensing doctors, should provision of services under the revised terms of services be mandatory, or should pharmacy contractors and dispensing doctors be able to choose to continue to provide them under their current terms of service?

Comments:

7. What level of training and experience should contractors carrying out home visits possess?

Comments:

8. Are clinical governance aspects covered to the appropriate level of detail i.e. are they too thorough or not thorough enough?

Comments:

9. We intend to introduce the new sub-categories detailed in this document into the Drug Tariff. What is your view on the suitability of the sub-categories proposed for the grouping of functionally equivalent products?

Comments:

10. Are there any sub-categories that should be added to this list?

Comments:

11. Should any of the sub-categories be broken down further i.e. are these descriptions not detailed enough to define a group of functionally equivalent products?

Comments:

12. Is it possible to merge any of the sub-categories together to create broader sub-categories of functionally equivalent products?

Comments:

13. Do you have any general comments relating to these consultation issues?

Comments: