National Procurement

NHS National Services Scotland

SPECIFICATION OF REQUIREMENTS

for

STOMA APPLIANCES IN THE COMMUNITY

Applicable from: 1st July 2018 to 30th June 2020

This is a continuation of the previous arrangement

Return Date: Friday 27 July 2018, or sooner

Please return this document as soon as possible with the relevant and requested information, particularly the signed and completed docquet as detailed in Appendix 1. Prospective Stoma Appliance Suppliers should aim for completion and return within 4 weeks of receipt.

Date Issued: June 2018

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INTRODUCTION

This document sets out the standards to be met by all Stoma Appliance Suppliers for the purposes of being placed on a list of approved suppliers authorised to supply Stoma Appliances to patients in the community via the Stoma Service Suppliers. Failure to continue to meet the standards set out in this document, as assessed on behalf of Scottish Government by National Procurement, a division of the Common Services Agency, a statutory body constituted pursuant to the National Health Service (Scotland) Act 1978 and having its headquarters at Gyle Square, 1 South Gyle Crescent, Edinburgh, EH12 9EB ("the Common Services Agency") may result in such parties being removed from the list of approved suppliers.

This is a continuation of the arrangements previously put in place in March 2014.

1. DEFINED TERMS AND INTERPRETATION

1.1 In this Specification of Requirements document, the following terms shall have the following meanings ascribed to them:

"1978 Act"	means the National Health service (Scotland) Act 1978;
"Authority"	means the Common Services Agency (whose divisions include National Procurement (NP), Practitioner Services Division (PSD) and Information and Statistics Division (ISD)
"DoH"	means English Department of Health
"GDPR"	means the General Data Protection Regulations 2016
"ISD"	mean the Information and Statistics Division, a division of the Common Services Agency;
"NP"	mean National Procurement, a division of the Common Services Agency;
"PSD"	means the Practitioner Services Division of the Common Services Agency;
"SG"	means Scottish Government;
"Stoma Appliances"	the list of stoma appliance products from time to time in force as maintained by ISD and published on its web site and which may be prescribed by authorised prescribers.
"Stoma Appliance Suppliers"	means suppliers and/or manufacturers of Stoma Appliances.
"Stoma service suppliers"	means collectively DACs and Community Pharmacy Contractors.
"DAC"	means Dispensing Appliance Contractor
GP10	means the GP10 Prescription form
VFM	means value for money
HBP	means a Prescription issued by a Health Board from an appropriately qualified medical and/or nursing staff.

2. POSITION OF THE AUTHORITY

2.1 Stoma Appliances are no longer listed in the Scottish Drug Tariff issued pursuant to the 1978 Act for the supply of Stoma Appliances to patients in the community in Scotland, and accordingly fall out with the scope of Pharmaceutical Services. NP maintains a list of approved Stoma Appliance Suppliers who will be entitled to supply Stoma Appliances to Stoma services suppliers.

2.2 As a condition of being placed on a list of Stoma Appliance Suppliers entitled to supply Stoma Appliances to patients within NHS Scotland, Stoma Appliance Suppliers must agree to meet the standards set out in this document for the supply of Stoma Appliances and provide details of pricing arrangements for Stoma Appliances on the basis detailed in this Specification Document. Stoma Appliance Suppliers must indicate their commitment to meet those standards by:

2.2.1. Signing one copy of this Specification Document (Appendix 1) where indicated and returning that signed copy to NP

2.2.2. Returning the proposed pricing of Stoma Appliances for the duration of the period by completion of the Pricing Information Spreadsheet (Appendix 2)

2.2.3 Acceptance of the rebate proposal or submission of an alternative proposal as requested in this document.

2.3 Failure to return these documents duly signed by an appropriate authorised officer of the Stoma Supplier undertaking to meet the required standards and conditions will exclude a supplier from the list.

3. SCOPE

3.1 This document applies solely to the supply of items considered to be Stoma Appliances which fall within the following categories and which may be prescribed by authorised prescribers:

3.1.1. Adhesive discs/rings/pads/plasters
3.1.2. Adhesive pastes/sprays/solutions
3.1.3. Adhesive removers (sprays, liquids, wipes)
3.1.4. Bag closures (available separately from bags)
3.1.5. Bag covers
3.1.6. Belts
3.1.7. Colostomy bags
3.1.8. Deodorants
3.1.9. Discharge solidifying agents
3.1.10. Filters/bridges
3.1.11. Ileostomy bags
3.1.12. Irrigation/wash-out appliances (replacement parts)
3.1.13. Pressure plates/shields
3.1.14. Skin fillers and protectives
3.1.15. Skin protectors
3.1.16. Stoma caps/dressings
3.1.17. Tubing and accessories stoma
3.1.18. Two piece ostomy systems
3.1.19. Urostomy bags
3.1.20. Wound management products (when used in connection with other stoma appliance items)

4. TIME / DELIVERY

Stoma Appliance Suppliers must undertake to:

4.1 Ensure adequate stocks of Stoma Appliances are held to facilitate prompt supply for repeat

requests and appropriate supply lines are established for items only intermittently required;

4.2 Ensure appropriate quantities of complementary supplies of disposal bags and wipes are provided free of charge to patients through the relevant Stoma Service Supplier; and

4.3 Provide information to NP about their arrangements for the provision of exceptional urgent provision including all supplementary costs such as minimum order and delivery charges which Stoma service suppliers may be expected to pay and absorb.

5. IDENTIFICATION OF GOODS & TRACEABILITY

5.1 Stoma Appliance Suppliers will ensure that information regarding batch codes of Stoma Appliances are recorded and retained for a period of no less than one year from the last date of delivery to enable checks to be made on such remaining stocks to be traced in the event of a series of complaints or product recall.

6. AGREEMENT PRICE AND PAYMENT

6.1 Reimbursement of the Gross Ingredient Cost of Stoma Appliances covered by this document dispensed against GP10 or HBP series prescriptions will be made to Stoma Service Suppliers at the pricing notified to National Procurement by Stoma Appliance Suppliers in response to this specification of requirements. The Pricing Information Spreadsheet (Appendix 2) should be completed and returned (electronically).

6.2 It is considered that there are efficiencies of scale in providing Stoma Appliances in large volumes which should be shared by Stoma Appliance Suppliers with NHS Scotland. The introduction of a retrospective discount claw back scale, or equivalent mechanism put forward by the Stoma Appliance Supplier, is to apply to each Stoma Appliance Supplier to ensure this benefit is transferred directly to the Health Boards based on actual business received. This process is detailed in section 6.3 below.

6.3 Stoma Appliance Suppliers are required to

6.3.1 Adhere to the sliding scale pricing structure as set out below in Table 1 which is based on market share within NHS Scotland. This will be calculated retrospectively i.e. payment would take place at the fees stated in Table 1 and a calculation carried out each year of any applicable claw backs that were due.

6.3.2 The income relating to Stoma Appliances dispensed to NHS Scotland with each Stoma Appliance Supplier would be measured on an annual basis using data provided by ISD. The next 2 years of measure will be 1st January 2017 – 31st December 2017 and 1st January 2018 – 31st December 2018. Stoma Appliance Suppliers supplying under the terms of this document will then pay a retrospective discount calculated as detailed in Table 1, shared between NHS Scotland Health Boards in proportion to each Health Board's overall share of the dispensed Stoma Appliances with the Stoma Appliance Supplier concerned over the time period covered.

6.3.3 The claw back calculation will be carried out on an annual basis (once data is available from ISD) using data provided by ISD or other metric as required by the accepted supplier proposals. Once agreed with each specific supplier a cheque is to be made out to "NHS National Services Scotland" where an element of reimbursement is required.

6.3.4 Table 1 – Sliding Scale Claw back

Market Share (see below for explanation)	Claw back % (see below for explanation)
<5%	Nil
5% to 10%	2.5%

10% to 15%	5%
15% to 20%	10%
20% +	Min 10%

6.3.5 Market Share Explanation

Market Share for Supplier A = Total Value of Dispensed Stoma Appliances for Supplier A for the period / Total Value of Dispensed Stoma Appliances for All Suppliers for the period

6.3.6 Claw back % Explanation.

Claw back % is the percentage to be applied to the Total Value of Dispensed Stoma Appliances for the Supplier concerned for the period.

6.3.7. Suppliers can also provide an alternative sliding scale or other programme of benefits designed by the Stoma Appliance Supplier that is demonstrated by submitted evidence and agreed as equivalent by an appropriate NHS Scotland representative (clinical, financial, health economist or other appropriately informed public sector person). This VFM proposition will be reviewed in comparison to the benefits that may be accrued from the sliding scale in Table 1 for the specific Stoma Appliance Supplier submitting the proposal and in the context of the overall VFM of the proposal from the Stoma Appliance Supplier concerned.

6.3.8 For any alternative sliding scale / programme offered as per 6.3.7, a document must be submitted to NP detailing the alternative programme of benefits for NHS Scotland. This document must also quantify how the proposal compares with the price, and if appropriate non-price benefits, available in other parts of the UK / Europe, that the Stoma Appliance Supplier is providing but NHS Scotland are not taking or unable to take advantage of.

6.3.9 The total benefit (claw back plus VfM alternative) must meet the total value as calculated in table 1 above.

7. LEGISLATIVE

7.1 All Stoma Suppliers must comply with all relevant legislation including, but not limited to, legislation relating to advertising and marketing, the sale of goods, relevant European Directives/Regulations, consumer rights, disability rights, and GDPR, Consumer Protection from Unfair Trading Regulations 2008 and the Consumer Credit (Advertisements) Regulations 2004 as amended.

8. CHANGE CONTROL

8.1 NSS shall maintain the approved list of Stoma Appliance Suppliers on an open basis. This means additional Stoma Appliance Suppliers may be added at any time providing they can demonstrate that they can meet the requirements of this Specification Document and provide the pricing information required in respect of supply of Stoma appliances require herein.

8.2 Stoma Appliance Suppliers may be removed from the approved list if they fail to meet the requirements of this document.

8.3. Change to Stoma Appliances during the period 1st July 2018 to 30th June 2020

8.3.1 Any changes to the Stoma Appliance Supplier's product listing occurring after return of this Specification Document by any Stoma Appliance Supplier will be added to the List of Stoma Products.

8.3.2 It should be noted that submissions will be subject to assessment by National Procurement of VFM criteria. Clinical evidence such as published papers, case studies, references, business models will be requested and taken into account if provided; otherwise, a like for like comparison will be carried out with similar products.

8.3.3 Lists of new Stoma Appliances requested to be added to the approved list should be sent to NP (no samples). An application form is included in Appendix 3.

8.4 To determine whether or not to allow a new product to be dispensed to patients in NHS Scotland an NP commodity manager will carry out initial VFM review based on documentation (not Stoma Appliances) submitted by Stoma Appliance Suppliers in accordance with the provisions above. In making its assessment NP may seek advice from clinical staff within NHS Scotland as required.

8.5 If a Stoma Appliance Supplier wishes to appeal against a decision made by NP in terms of a decision, aforesaid such appeal should be directed to the NP Clinical Director for review of the decision.

9. QUALITY

9.1 By signing this document, Stoma Appliance Suppliers warrant that all Stoma Appliances provided by them shall conform to all relevant standards, specifications and conditions, and that Stoma Appliance Suppliers shall perform all obligations incumbent upon them in terms of this document in accordance with best industry standards and practice. All Stoma Appliances supplied to patients (via the Stoma Service Suppliers) shall be sufficient for the purpose for which they are ordinarily used and for any particular purpose made known by the Stoma Supplier to patients and/or Stoma Service Suppliers.

9.2 By execution of this document, Stoma Appliance Suppliers hereby indemnify and hold harmless Scottish Health Boards against any damages, losses, liabilities, costs, expenses (including the cost of legal or professional services (including the cost of disbursements)), charges and penalties arising directly as a result of failure by the Stoma Supplier to supply goods in accordance with the provisions of this document.

10. REMOVAL FROM THE LIST OF APPROVED STOMA APPLIANCE SUPPLIERS

10.1 NP may remove a Stoma Appliance Supplier from the list of approved Stoma Appliance Suppliers if performance falls short of the standards and requirements set out in this document and the Stoma Appliance Supplier concerned has not rectified any deficiencies identified and notified to it by NP within the period specified by NP (acting reasonably) for such rectification.

11. CONFIDENTIALITY

11.1 The Authority shall keep confidential information provided by Stoma Appliance Suppliers in connection with this document and shall only use such information for the purposes stated herein. The obligation of confidentiality shall not apply to any information which:

11.1.1 was known to the Authority prior to receipt either directly or indirectly from the Stoma Appliance supplier; or

11.1.2 is or becomes available to the public through no fault of the Authority; or

11.1.3 is required to be disclosed pursuant to an order of court of competent jurisdiction or applicable law or regulation; or

11.1.4 is subsequently disclosed to the Authority without restriction by a third party having the lawful right to make such disclosure; or

11.1.5 is not exempt from disclosure under the Freedom of Information (Scotland) Act 2002 and/or any codes of practice issued thereunder.

12. DATA PROTECTION

12.1 All Stoma Appliance Suppliers undertake to comply fully with GDPR requirements and failure to

do so may result in removal of a Stoma Appliance Supplier from the list of approved Stoma Appliance Suppliers.

Example APPENDIX 1 – RETURN DOCQUET

SPECIFICATION OF REQUIREMENTS

for

STOMA APPLIANCES IN THE COMMUNITY

Applicable from: 1st July 2018 to 30th June 2020

I, [***insert name and designation***] hereby confirm I am a duly authorised representative of [***name of Stoma Appliance Supplier***] and that I have all necessary authority to sign this document on behalf of [***insert name of Stoma Appliance Supplier***].

On behalf of [***insert name of Stoma Appliance Supplier***], I hereby confirm that [***insert name of Stoma Appliance Supplier***] accepts that its appointment to the list of authorised Stoma Appliance suppliers shall be subject to [***insert name of Stoma Appliance Supplier***] meeting and continuing to meet the standards and procedures set out in this document relating to the supply of Stoma Appliances to patients through the Stoma Service Suppliers, and [***insert name of Stoma Appliance Supplier***] agrees to abide by the terms of this document in such supply.

Date: .....

Signed by: .....

Print Name: .....

Designation: .....

Stoma Appliance Supplier Name: …….

Address Line 1: …….

Address Line 2: …….

Address Line 3: …….

Address Line 4: …….

Post Code: …….. Tel No. ……..……..…

Contact Name: ……..……..…

Position: ……..……..…

E-mail Address: ……..……..…

Return Address:

Paul Dishington - Commodity Specialist
National Procurement
Gyle Square (NSS Head Office), 1 South Gyle Crescent
Edinburgh EH12 9EB
E-mail Address: pauldishington@nhs.net

APPENDIX 1 – RETURN DOCQUET

SPECIFICATION OF REQUIREMENTS

for

STOMA APPLIANCES IN THE COMMUNITY

Applicable from: 1st July 2018 to 30th June 2020

I hereby confirm I am a duly authorised representative of and that I have all necessary authority to sign this document on behalf of . On behalf of , I hereby confirm that accepts that its appointment to the list of authorised Stoma Appliance suppliers shall be subject to meeting and continuing to meet the standards and procedures set out in this document relating to the supply of Stoma Appliances to patients through the Stoma Service Suppliers, and agrees to abide by the terms of this document in such supply.

Date: .....

Signed by: .....

Print Name: .....

Designation: .....

Stoma Appliance Supplier Name: …….

Address Line 1: …….

Address Line 2: …….

Address Line 3: …….

Address Line 4: …….

Post Code: …….. Tel No.: ……..

Contact Name: ……

Position: ……

E-mail Address: ……

Return Address:

Paul Dishington - Commodity Specialist
National Procurement
Gyle Square (NSS Head Office), 1 South Gyle Crescent
Edinburgh EH12 9EB
E-mail Address: pauldishington@nhs.net

Stoma Appliances

1.	Details of Applicant and manufacturer (if different)	
	Name and address of applicant	Name and address of manufacturer
2.	Product Name State the trade name under which the product is to be launched, or is already known in the UK.	
3.	General Description of product (including Scottish Stoma Listing category e.g. Flanges)	
4.	Proposed pack sizes, prices and order codes (e.g. 1x30 - £7.50 – code 00123)	
5.	All products should be CE marked. Give details of compliance with Drug Tariff Specifications, British Standard or British Pharmacopoeia and quality assurance systems used drug manufacture. Please attach a certificate of evidence from accredited independent testing house.	
6.	Classification of CE marked product (where applicable)	
7.	Please state the annual anticipated volume of sales in Scotland.	
8.	Contra-indication and any other limitations to use	
9.	Please confirm that the product will be readily available to the community pharmacist either through the normal pharmaceutical wholesale network or on equivalent terms.	

10.	Please advise if this product is replacing another product currently on the List of Stoma Products. If so, give details of the product to be replaced.
11.	If this item is to be removed from the List of Stoma Products, please give an indication of the proposed timescales.
12.	Is the new product an extension to an existing range? If so give details.
13.	Has a clinical trial of the product been carried out? If so, please advise dates and location. Please also supply documents detailing results of the trial.
14.	Has your product already been approved for addition to the English and Welsh Drug Tariff? Please indicate the approval date and which heading it was included under.

Signatory
The application should be signed by a senior person in the company

Signature..... Date.....

Name in block capitals.....

Position in the company.....

Please send your application to:

Paul Dishington - Commodity Specialist
National Procurement
Gyle Square (NSS Head Office), 1 South Gyle Crescent
Edinburgh EH12 9EB
E-mail Address: pauldishington@nhs.net