RM6187 Framework Schedule 6 (Order Form and Call-Off Schedules)

Order Form

CALL-OFF REFERENCE:	**C301728**
THE BUYER:	Department of Health and Social Care
BUYER ADDRESS	39 Victoria Street, London SW1H 0EU
THE SUPPLIER:	PA Consulting Services Ltd
SUPPLIER ADDRESS:	10 Bressenden Place, London, SW1E 5DN
REGISTRATION NUMBER:	00414220
DUNS NUMBER:	**211000617**
SID4GOV ID:	**TBC**

Applicable framework contract
This Order Form is for the provision of the Call-Off Deliverables and proposal from supplier dated 19 April 2024.
It's issued under the Framework Contract with the reference number RM6187 for the provision of Medtech In the Community Services.

CALL-OFF LOT(S): Lot 3

Call-off incorporated terms
The following documents are incorporated into this Call-Off Contract.
Where schedules are missing, those schedules are not part of the agreement and can not be used. If the documents conflict, the following order of precedence applies:

1. This Order Form includes the Call-Off Special Terms and Call-Off Special Schedules.
2. Joint Schedule 1(Definitions and Interpretation) RM6187
3. The following Schedules in equal order of precedence:

Joint Schedules for RM6187 Management Consultancy Framework Three

- Joint Schedule 1 (Definitions) - Mandatory

- Joint Schedule 2 (Variation Form) - Mandatory
- Joint Schedule 3 (Insurance Requirements) - Mandatory
- Joint Schedule 4 (Commercially Sensitive Information) - Mandatory
- Joint Schedule 6 (Key Subcontractors) - Optional
- Joint Schedule 10 (Rectification Plan) - Mandatory
- Joint Schedule 11 (Processing Data) - Mandatory

Call-Off Schedules

- Call-Off Schedule 5 (Pricing Details)
- Call-Off Schedule 9 (Short form Security)
- Call-Off Schedule 20 (Call-Off Specification)

4. CCS Core Terms
5. Joint Schedule 5 (Corporate Social Responsibility) - Mandatory
6. Call-Off Schedule 4 (Call-Off Tender) as long as any parts of the Call-Off Tender that offer a better commercial position for the Buyer (as decided by the Buyer) take precedence over the documents above**.**

Supplier terms are not part of the Call-Off Contract. That includes any terms written on the back of, added to this Order Form, or presented at the time of delivery.

Call-off special terms

The following Special Terms are incorporated into this Call-Off Contract:

Special Term 1 - The Buyer is only liable to reimburse the Supplier for any expense or any disbursement which is

(i) specified in this Contract or
(ii) which the Buyer has Approved prior to the Supplier incurring that expense or that disbursement. The Supplier may not invoice the Buyer for any other expenses or any other disbursements

None.

Call-off start date: **19 August 2024**

Call-off expiry date: **20 December 2024**

Call-off initial period: 4 months.

Call-off deliverables:

From the response to the specification (Call-off 20)

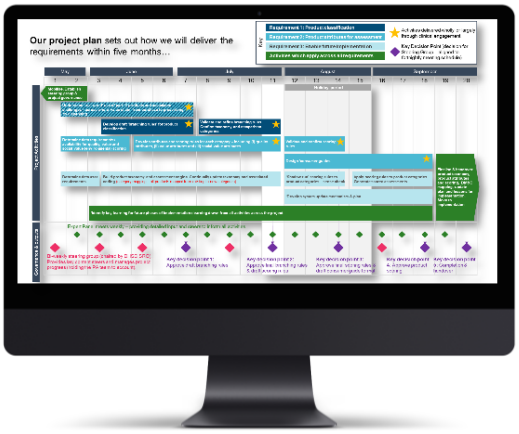
PA Consulting Services Ltd overall approach (as per tender)

The key features of our approach are:

- A classification system and series of product attributes driven by 'on the ground' clinical and patient experience of Part IX
- A proven and rigorous analytical approach
- Flexibility to test, iterate and refine
- Gathering learning, transferring knowledge and looking ahead to implementation throughout

Key delivery activities:

We will deliver the project through three overlapping workstreams, broadly aligned to your 'requirements' but with some cross-cutting elements. Our project plan is included separately. Below is the summary of the key activities in each workstream.



Also provided separately are our initial view on:

- Product classification (requirement 1); and
- Quality and social value attributes (requirement 2)

These are intended to provide a starting point for further analysis, allowing us to accelerate early discussions.

Requirement 1: Product classification	Engagement with clinicians, patients and industry to understand 'real world' use of Part IX products and associated challenges: (i) Interviews with prescribers and dispensers, suppliers, wholesalers and patient representatives; (ii) Review literature, local formularies and clinical system taxonomies, to identify how products are grouped, and which are considered 'clinically comparable' now; and (iii) Use ThoughtExchange to canvas widespread clinical opinion on product categories and scoring rules. We have used this flexible online tool very successfully on many assignments, including our recent review of the National Wound Care Strategy Programme. Develop and refine 'branching rules' for the product taxonomy: (i) Translate engagement insights into draft 'branching rules' to generate the overall taxonomy and categories. (ii) Applying draft rules to all current Part IX products to 'test run' emerging categories. (iii) Refine the rules in each category to define a final taxonomy which is (i) understandable and aligned to 'real world' clinical practice; and (ii) provides categories suitable for scoring and generation of consumer guides. Design 'consumer guides' including considering: (i) *End-user preferences*: Using insights from SMEs and engagement. (ii) *Data availability*: Ensuring required data is available to populate the guides. *Market considerations*: Ensuring all products are presented fairly and avoiding market distortions.

Requirement 2: Product attributes for assessment	**Develop and confirm scoring rules for each category:** (i) **Combine engagement insights with available data, to generate draft scoring rules by category.** We anticipate that 'value' and 'social value' will be scored in a consistent way across categories (with adaptations), but that 'quality' will be defined on a category-by-category basis. (ii) **Applying the draft scoring rules to priority categories** to 'test run' scoring. (iii) **Review with the clinical panel** to identify potential anomalies. (iv) Develop a **system update mechanism & plan**, to include (i) timing of updates; (ii) approach to implementing updates; and (iii) ownership of the update mechanism.
Requirement 3: Enable future implementation	**Build the product taxonomy and classification tool**: (i) **Coding of a flexible, scalable taxonomy**: We will work with you to formulate specific requirements relating to assumptions capture and change control, and then build these into the tool. *(ii)* **A dynamic search tool**: tools will emphasise convenience and flexibility, for example, allowing selected products and their clinically equivalent peers to be quickly identified and compared, *with associated coding.* (iii) Visualisations to help observe patterns in classification and to spot any unexpected behaviours. **Apply scoring rules to product groups:** **Sensitivity analysis, exploratory data analysis and 'spot checks'** by the SME panel.
Cross-cutting activities	(i) **Establish the SME Panel:** The Panel will provide detailed expert input to all activities. We will work with you to establish panel membership, including both PA and DHSC SMEs, in order to ensure maximum credibility and insight. (ii) **Key learning for future phases.** We will maintain an ongoing log of learning, periodic 'reflection sessions' with the SME panel and steering group, and incorporate learning within our assessment approach. **Finalise and handover product taxonomy, product attributes and scoring, DM&D mapping, update plan and lessons for implementation.** **End of Sept 2024**

Accountability, reporting and risk management

Security

Short form security requirements apply **and**
Security Policy.

Maximum liability

The limitation of liability for this Call-Off Contract is stated in Clause 11.2 of the Core Terms.

The Estimated Year 1 Charges used to calculate liability in the first contract year are: [redacted]

Call-off charges

The Charges for the Deliverables**.**

As per details below;

MedTech in the Community-Part IX	**Pricing Schedule**

Activity	Item	Total cost
1	Product Classification: A report setting out the new categorisation for Part IX. Separate funds are available so we can pay for clinicial and patient input. 'Consumer guides' for these product groups (Website and leaflet form) (does not include cost of printing leaflets but e.g. a pdf available for GPs to print)	[redacted]
2	Develop product attributes for assessment including report with recommendations assessing quality and social value attributes and propose how we can keep them up to date	[redacted]

3	Enable future implementation: a spreadsheet with all categories mapped	[redacted]
Total		[redacted]

Personnel and Activity Tab					
Personnel Name	**Grade**	**Rate (£) per day**	**Activity**	**Days (Number)**	**Total (£)**
[redacted]	[redacted]	£ [redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	£ [redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Note: example shown above.
All prices to include for travel and expenses

Sub-total	£ [redacted]
Discount	£ [redacted]
FINAL OFFER PRICE	**£** [redacted]

All changes to the Charges must use procedures that are equivalent to those in Paragraphs 4, 5 and 6 (if used) in Framework Schedule 3 (Framework Prices)

The Charges will not be impacted by any change to the Framework Prices. The Charges can only be changed by agreement in writing between the Buyer and the Supplier because of:

- Specific Change in Law
- Benchmarking using Call-Off Schedule 16 (Benchmarking)

Reimbursable expenses
Recoverable as stated in Framework Schedule 3 (Framework Prices) paragraph 4.

Payment method
All invoices must be sent, quoting a valid Purchase Order Number (PO Number) and any other relevant details, to:
Payment of undisputed invoices will be made within 30 days of receipt of invoice, which must be submitted promptly by the Supplier.

Buyer's invoice address
DHSC Accounts Payable

FINANCIAL TRANSPARENCY OBJECTIVES
The Financial Transparency Objectives apply to this Call-Off Contract.

Buyer's authorised representative

Buyer's security policy
Short form applies.

Supplier's authorised representative

Supplier's contract manager

Progress report frequency
On the first Working Day fortnightly or as advised by DHSC contract manager.

Progress meeting frequency
Weekly, or as advised by DHSC contract manager.

Key staff

[redacted]

Key subcontractor(s)

PA Holdings Limited

Commercially sensitive information

[redacted]

Service credits

Not applicable.

Additional insurances

Not applicable**.**

Guarantee

Not applicable.

Buyer's environmental and social value policy

N/A

Social value commitment

The Supplier agrees, in providing the Deliverables and performing its obligations under the Call-Off Contract, that it will comply with the social value commitments in Call-Off Schedule 4 (Call-Off Tender)]

Formation of call off contract

By signing and returning this Call-Off Order Form the Supplier agrees to enter a Call-Off Contract with the Buyer to provide the Services in accordance with the Call-Off Order Form and the Call-Off Terms.

The Parties hereby acknowledge and agree that they have read the Call-Off Order Form and the Call-Off Terms and by signing below agree to be bound by this Call-Off Contract.

For and on behalf of the Supplier:

Signature: [redacted]

Name: [redacted]

Role: [redacted]

Date: 19/08/2024

For and on behalf of the Buyer:

Signature: [redacted]

Name: [redacted]

Role: [redacted]

Date: 20/08/2024

Order Schedule 20 (Order Specification)

This Schedule sets out the characteristics of the Deliverables that the Supplier will be required to make to the Buyers under this Order Contract

Purpose

The purpose of this document is to explain the different components of the MedTech in the Community work being tendered for. The Medtech and Innovation Directorate in the Department of Health and Social Care have recently consulted on updates to Part IX of the Drug Tariff. This work specification will not currently be implemented but is to inform policy decisions, along with consultation feedback, on whether this is implemented and in what form.

Background

'MedTech in the community' refers to medical devices (also known as appliances) that are appropriate for use outside of a hospital setting.

There are different supply and distribution routes in the community including off-prescription, for example a local procurement may be carried out. For appliances to be prescribed with electronic prescription/FP10 form they must be listed on Part IX of the Drug Tariff. Part IX contains a list of appliances and chemical reagents approved by NHS Prescription Services on behalf of the Secretary of State for Health for prescribing at NHS expense by an appropriate practitioner. The Drug Tariff therefore has statutory footing. It outlines what contractors will be paid for providing NHS services i.e., for reimbursement (including costs of drugs, appliances etc.) and remuneration as part of a dispensing contract.

As part of the application for Part IX, NHS Prescription Services determines where on the Drug Tariff the appliance fits.

Part IX has four subcategories:

1. Part IXa – Appliances (includes wound care, eye care products, lymphoedema garments, tracheotomy products)
2. Part IXb – Incontinence appliances
3. Part IXc – Stoma appliances
4. Part IXr – Reagents – blood glucose testing strips

Requirements/outputs of this work:

1. **Product classification:** To enable clear, structured understanding of what products are (and are not) broadly clinically comparable by implementing a clinically led classification system.
2. **Develop product attributes for assessment:** To determine the quality attributes and the social value attributes that should apply to these products.
3. **Enable future implementation:** this requires mapping any changes in classification so that NHSBSA can later make the coding changes (if we take forward). This also requires modelling the impact of price changes once the attributes for a category are determined and the benchmark price can be determined so that policy team can decide what to take forward.

Product classification:

Context

- The Drug Tariff is not in itself an endorsement of the appliances. The application criteria are that the appliance is: safe and of good quality; it is appropriate for GP and, if relevant, non-medical prescribing; and it is cost-effective (compared to similar products on the Tariff).
- There is a huge amount of 'choice' within some categories of product. However, this does not come across as 'meaningful choice' as there is not a clear, unbiased way to compare all the products.
- As of October 2022, Part IX contained the following:

Part IX Section	Lines Covered	Total Lines	Main Products
IXA	2 – 53,889	53,888	• Approx. 45,000 of these items are lymphoedema garments • 1724 items are catheters • The remainder (7,164 items) includes wound care, stoma (tracheostomy) products, eye drops, ear drops, emollients, insulin needles and lancets, contraceptive devices and sexual dysfunction devices
IXB	53,890 – 55,285	1,396	Continence (except Catheters, listed on Part IXA)
IXB and IXC	55,286 – 55,291	6	Ostomy adhesives
IXC	55,292 – 64,774	9,483	Stoma (except tracheostomy products, listed on Part IXA)
IXR	64,775 – 64,879	105	Reagents testing strips

- Wound care products are currently being classified by the National Wound Care Strategy Programme -Supply and Distribution Workstream so are out of scope for categorisation.

Outputs

- **Coordination with clinical leaders** across the system and patient representatives who are able to determine classification standards, an evaluation methodology and consider them alongside international classification systems and other coding structures.
- **A classification system** with a clinical hierarchy of standards for different classes of product specifications. All products listed on Part IX should be classified (if appropriate) except for wound care products. Each bucket created should contain interchangeable appliances and be clinically comparable. This is expected to cover all existing products on Part IX of the Drug Tariff for the relevant clinical area (stoma etc.) as well as other appliances regularly used in the community for that clinical area. The exception is wound care products as there is already a programme of work classifying wound care.
- **All relevant products are assigned into a category**; and any changes from the Drug Tariff are mapped so it is clear if they have moved from a category and if the existing category on the tariff has changed name. This should set out the current codes (GTIN, SNOMED and GMDN) for the products and will set out how they have moved under the proposed categorisation system (where relevant) and what their new position will be (Part IX products are not currently categorised by GMDN). Tracking the codes is important for future implementation as it requires NHS Business Services Authority (NHSBSA) to re author products on their database. Wound care products are in scope for tracking positions.
- **A defined methodology** clearly accessible and outlined in a format such as a data dictionary and data standards to determine which category new product applications belong to and how they can be evaluated.
- **'Consumer' Guides** to include description of product types and typical product use and how this might change over time; this should be aimed at prescribers and at patients; both website and leaflet format; it should include an explanation of supply routes of products so that patients understand the choices they have of where to source their products from. For prescribers it should include guidance on an approach to value for money of these products. Wound care products are also in scope for the guides.

Develop product attributes for assessment:
Context

Given the number of similar appliances, we are exploring whether a method of comparing these appliances needs to be introduced. This should be free of industry influence and led by clinical recommendations and patient feedback. It should be clear what elements of these products are being recommended, e.g. the technical elements and patient usage experience. They do not need to be the cheapest products, but cost-effectiveness should be considered in forming the methodology for evaluation. The guide would compare evidence between products and consider patient outcomes

and cost; this may highlight those products that have the same outcomes but there are unnecessary price differences between them.

Outputs (Wound care products are in scope for this)

- **Identify quality attributes:** this should take into account requirements for CE/UKCA markings, clinical and patient feedback.
- **Identify social value attributes:** our consultation proposed that we will develop environmental attributes applicable at product level (not to the company as a whole). These should align/not conflict with world trade agreements.
- **Identify how these attributes can feasibly be applied:** The consultation has proposed a scoring system based on number of quality attributes that assessment should be tested against so that we can determine if and how to implement.
- **Stakeholder engagement:** To ensure attributes are understood by industry, clinicians and patients/users and can be feasibly applied.
- **Identify key learnings from this work** including recommendations for assessing quality and social value attributes.
- **Maintenance:** propose an approach which ensures that the attributes that are established remain up to date.

Enable future implementation:

Context

- Reimbursement and price of products on Part IX are determined by where they are placed within Part IX. The first product into a category sets the price as any further products are assessed for cost-effectiveness against the others in that category. If a product is agreed to be different enough to open a new category, then a new price can be set. By moving products based on re-classification it means that price changes need to be assessed.
- Part IX is a statutory list therefore policy updates are required to introduce new rules. Currently we cannot simply remove products from Part IX because we have deemed them unsuitable for prescription. Products that are discontinued can and are removed from Part IX either when identified by the NHS BSA team or notified by the supplier.
- The dictionary of medicines and devices (DM+D) holds descriptions and codes of medicines and devices in use across the NHS. Information that sits on Part IX of the Drug Tariff such as the indicative price is based on information from DM+D. The dictionary is a standalone product but is integrated with SNOMED CT codes. This standardisation is encouraged throughout NHS systems and DM+D is used in prescribing systems, pharmacy dispensing systems, electronic prescription service, Summary Care Records, the Yellow Card scheme and others. Therefore, if any changes to product classification are identified they must be changed at DM+D level.
- Dispensing Appliance Contractors (DACs) operate their own dispensing systems. Part IX updates are incorporated into these systems but are not owned by DHSC.
- For the electronic prescription system to function dm+d needs to be aligned. If a DAC system does not recognise a code being prescribed it cannot meet the prescription request for the patient.

Outputs (Wound care products are in scope for this)

- **Category mapping:** All product moves should be mapped from existing categories on Part IX to new category (so that NHSBSA can implement changes if taken forward). This will set out the current codes (GTIN, SNOMED and GMDN) for the products and will set out how they have moved under the proposed categorisation system (where relevant).