Appendix 3 – Framework Agreement Specification

Physiotherapy and Occupational Therapy

SECTION A – General Requirements

1. Introduction

1.1. Supply Chain Coordination Limited are seeking to establish a multi-supplier framework for the supply of Physiotherapy and Occupational Therapy products to the NHS and its partner organisations.

1.2. The framework is to be available for use by NHS Trusts and other UK public sector bodies in England, Scotland, Wales, and Northern Ireland including those operating in both an acute and community environment, clinical commissioning groups, GP Practices and other health and social care providers (including any future successor organisations). The framework will be available for use by the Ministry of Defence, Clinical Commissioning Groups (CCGs) and Integrated Care Systems (ICSs) or equivalent.

1.3. Schedule A6 shows a list of bodies eligible to use the framework.

1.4. It is intended that the framework will offer a comprehensive and wide range of suppliers and different products providing participating authorities the flexibility and choice in meeting specific needs and requirements. Participating authorities will have the option to procure products on an ad hoc basis or through more regular and structured bulk purchase arrangements.

1.5. The framework will provide a route to market fully compliant with Public Contracts Regulations enabling participating authorities to focus on their own specific requirements without the burden of cost and time in undertaking individual full procurement processes.

1.6. The framework is to be established based on a Lot structure below (Table 1) which summarises the structure of each Lot

Framework Structure

LOT Sub-Section	Physiotherapy and Occupational Therapy	
	LOT 1	LOT 2
0.1	Acupuncture	CPM Machines
0.2	Electrotherapy / Ultrasound Therapy	Large Exercise Machines / Equipment
0.3	General Exercise Equipment	Robotic Therapy
0.4	Hot and Cold Therapy	
0.5	Massage Products	
0.6	Posture & Balance	
0.7	Tapes, Strapping and Associated Products	

Table 1

2. Regulations, Standards and Legislation

2.1. All products being supplied under the framework must adhere to and comply with all relevant regulations, standards and legislation relating to each product including those amended, updated, or introduced during the term of the framework or any call off from it. This includes all relevant British Standards and European Directives.

2.2. Bidders successful in being awarded to the framework will be required to provide evidence of compliance to any regulations, standards, and legislation at the time of award and at any time either thereafter during the term of the framework or a call off from it by NHS Supply Chain or any participating authority.

2.3. Bidders will need to ensure that in delivering any of the requirements of the framework physical and sensory requirements of all service users are accounted for. Successful bidders will also need to adhere to Plain English Campaign (PEC) assurance standards

2.4. Specific regulations, standards and legislation relating to Lots are included in Table 2 below

Lot	Accreditation and/or Certification Requirements		
All Lots	BS EN ISO 9001-2015 or equivalent	Quality Management Systems. Requirements	Mandatory unless have BS EN ISO 13485:2016
	BS EN ISO 13485:2016 or equivalent	Quality management systems. Requirements for regulatory purposes.	Mandatory for manufacturer of medical devices, Class 1 sterile and above.
	Medical Devices Directive	All products must have their CE marking clearly evident on the product and /or packaging.	Mandatory, a valid certificate must in place for the duration of the framework agreement.
	93/42/EEC or equivalent	UKMDR is replacing MDD must be implemented by relevant dates.	

Lot	Accreditation and/or Certification Requirements		
	Medical Device Regulation (MDR 2017/745) or equivalent	MDR is acceptable until required to have UKMDR/UKCA mark.	
	UKCA/UKNI or equivalent	It is mandatory that the supplier complies with and supplies products in line with MDD and/or UKMDR mark regulations.	
		UKMDR is replacing MDD must be implemented by relevant dates.	
	COSHH Regulations 2002 (as amended) or equivalent	Control of Substances Hazardous to Health.	Mandatory for all substances that are hazardous to health this includes nanomaterials.
	Directive 2007/47/EC or equivalent	Products containing Phthalates must be indicated on packaging	Mandatory for all products containing Phthalates
	WEEE Directive 2012/19/EU or equivalent	Waste Electrical and Electronic Equipment	Mandatory for all Electrical and Electronic Equipment.
	ISO 14001:2015 or equivalent	Environmental management (EMS)	Desirable
	EC conformity EN 60601 or equivalent	Conformity Assessments	Mandatory
	Digital Technology Assessment Criteria (DTAC)	All digital health-based technology must meet the required standards	Mandatory, please provide completed DTAC assessment document for any digital health-based technology

Table 2

If the standard or legislation is mandatory, bidders must provide evidence that they comply with these

2.5. In accordance with the Control of Substances Hazardous to Health Regulations 2002 (as amended) safety data sheets for all product lines that fall under these Regulations must be provided by Applicants to NHS Supply Chain.

2.6. In accordance with the Digital Technology Assessment Criteria for health and social care (DTAC) all digital health technology products must be assessed and compliant. More information can be found at https://transform.england.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/

2.7. All product lines and packaging should be latex free where possible. If a product line contains latex this must be clearly labelled on the product line description and packaging (as applicable) to inform the user.

2.8. During the term of the Framework Agreement Applicants must make the authority aware of any awarded product line that is classed by the MHRA as a Medicinal Product.

3. Product / Packaging Features

3.1. Labelling and packaging must conform to all relevant British Standards and European Directives. Compliance with the GS1 coding standard is also required where appropriate. Further Information and guidance can be found at:

https://www.gs1uk.org/sites/default/files/gs1_uk_compliance_peppol_timeline_1.pdf

https://www.gov.uk/government/publications/nhs-e-procurement-strategy

3.2. Where possible clear and easy to follow symbols / diagrams / pictures are used to minimise reliance on text, aiding the clinician to accurately identify the product they need.

3.3. All packaging should provide suitable protection for bulk delivery. Where Packaging is damaged NHS Supply Chain reserve any rights to refuse any product damaged in transit.

3.4. Where size options exist, this must be displayed. When generic terms are used, it is desirable that they be accompanied by sizing information using metric/UK terms E.g., Medium = 40 to 50cm or Men's UK Size 7-9

3.5. On request, successful bidders will be required to provide documentary evidence to demonstrate compliance with the requirements of the Packaging (Essential Requirements) Regulations 2015 (as amended) which implements the EC Directive on Packaging and Packaging Waste (94/62/EC) in the UK, and which requires, packaging to be minimised, recoverable, and to not exceed by weight specified concentrations of heavy metals. Participating authorities are also expected to comply with the Regulations. Further guidance can be found on the Department of Trade and Industry's website at https://www.gov.uk/guidance/packaging-waste-become-a-packaging-producer-compliance-scheme-pcs

4. Additional requirements for all Lots

4.1. Participating authorities who use the framework may request product trials/evaluations. These are to be undertaken locally meeting the full requirements of participating authorities at no cost to them. The authority reserves the right to request product trails/evaluations at any time during the term of the framework.

4.2. Any proposed product changes or specifications relating to products covered by the framework will need to be agreed by the authority before continued inclusion on the framework. The authority reserves the right to request evidence of product and specification compliance at any time during the term of the framework.

4.3. Bidders successful in being awarded to the framework must ensure that any product recall or field safety notice issued by the Medicines and Healthcare products Regulatory Agency (MHRA) or any alert from NHS Improvement is actioned in accordance with relevant guidelines and reported to NHS Supply Chain and the authorised person/Medical Device Safety Officer (MDSO) in each participating authority.

4.4. Bidders successful in being awarded to the framework must ensure they have enough stock to meet agreed and expected service demands.

4.5. Bidders should give due consideration to the environmental impact of the products supplied under the framework and where possible continuous improvement techniques to identify and reduce the carbon footprint should be employed.

4.6. It is imperative that participating authority staff have access to a full range of products and size ranges. Therefore, the full range of products available to participating authority should be completed within the Offer Schedules.

4.7. The Provider must inform the participating authority and or the authority in writing of any proposed changes to the specification of existing products, Examples include.

- changes to packaging quantity or format

- product coding
- country of origin
- Manufacturing changes (materials, locations)

Notification of any such proposals shall be made at least three months prior to the proposed implementation date of any changes.

Additional Products

4.8. It is recognised that Bidders may be able to offer more than one product line or brand for each Lot. It is for Bidders to determine which of their products best meets the requirements of the specification for the purposes of evaluation and the full requirements of the ITT.

4.9. However, bidders successful in being awarded to the framework will be given the opportunity of including additional product lines relating to each Lot (or line where appropriate) they have been successful in being awarded to. Additional product lines will be considered post tender award and not as part of the tender process. Additional product lines will need to meet all minimum standards and minimum specification and performance requirements to be included as part of the framework.

5. Reopening of the Framework

5.1. The Authority is keen to ensure that this Framework Agreement continues to meet the needs of Participating Authorities by being able to continually offer the latest and most relevant products, technologies, and services to them. It recognises that over the term of a Framework Agreement, new innovative products may be developed by Suppliers on the Framework Agreement or by other new suppliers. The Authority also recognises that there could be issues with supply over the term of the Framework Agreement.

5.2. Therefore, in order to ensure that the Framework Agreement does not become obsolete/ suffer from supply issues, the Authority reserves the right (but is not obliged to) to reopen this Framework Agreement only in the following two circumstances:

- Product innovation/development; and
- Supplier Resilience

Product Innovation / Development

5.3. The process for product innovation/development is as follows:

5.3.1. Any supplier (either a Supplier or a new supplier) who can offer innovation or support changes to the market in relation to the product lines and services under this Framework Agreement (when originally procured), will have the opportunity to join the Framework Agreement on the second anniversary (2 years from the Commencement Date) or on the third anniversary (3 years from the Commencement Date) of the Framework Agreement, if the Framework Agreement is extended.

5.3.2. For avoidance of doubt, no new supplier and/or new product line and services will be able to join the Framework Agreement during the first 2 years of its term from the Commencement Date.

5.3.3. A Supplier or a new supplier who proposes any innovation or support changes to the market will have to meet and undertake the process set out at paragraph 5.4 in order to be considered for appointment to the Framework Agreement at the relevant times set out at paragraph 5.3.1.

5.3.4. If the Authority decides to extend the Framework Agreement, the Authority will notify the market of its intention to extend the Framework Agreement in line with the relevant advertising requirements at the time and via the Authority's eProcurement Platform.

5.4. Any Supplier (either a Supplier or a new supplier) who can offer innovation or support changes to the market to the Framework Agreement (when originally procured) will then have the opportunity if they meet the specified requirements in order to be considered for appointment to the Framework Agreement. These requirements are as follows:

5.4.1. The Supplier or a new supplier will need to submit any innovation or development ideas or proposals via the Authority's Innovation route, MedTech Mandation.

5.4.2. The Supplier's or the new supplier's innovation or development proposals and ideas must pass the MedTech Mandation route by deeming such a proposal or idea to be an innovation.

5.4.3. Meeting the evaluation criteria specified by the Authority which are currently set out in the Schedule A2 - Evaluation Methodology and Criteria.

5.4.4. Compliance to any specification and relevant industry standards.

5.4.5. Meeting non-financial and/or financial requirements relevant to the products and/or services supplier under the Framework Agreement (as determined by the Authority and this tender) and

5.4.6. Acceptance of the terms and conditions of the Framework Agreement without negotiation or amendment.

5.5. If the Supplier or new supplier is successful in meeting the requirements set out in paragraph 5.4, then that supplier will be awarded a contract under the Framework Agreement.

Supplier Resilience

5.6. The Authority recognises that there could be issues with supply over the term of the Framework Agreement. Such supply issues may be due to a Force Majeure Event or any event in which an existing Supplier is unable to supply a product line to the Participating Authorities ("**Supplier Resilience**").

5.7. The process for Supplier Resilience is as follows:

5.7.1. If, at any point during the Term of the Framework Agreement, the Authority identifies an issue in relation to Supplier Resilience to provide a particular product line, that they were originally awarded in any of the Lots, the Authority reserves the right to reopen the Framework Agreement in order to appoint a new supplier for that particular product line.

5.7.2. If, exiting Suppliers are able to provide that particular product line, the Authority also reserves the right to reopen the Framework Agreement.

5.7.3. If the Authority identifies that there is an issue with Supplier Resilience to provide product lines to the Participating Authorities, that such Supplier was originally awarded, the Authority will notify the market of its intention of reopening the Framework Agreement in line with the relevant advertising requirements at the time and via the Authority's eProcurement Platform and will allow any supplier the opportunity if they meet the specified requirements in order to be considered for appointment to the Framework Agreement. These requirements are as follows:

a) Meeting the evaluation criteria specified by Authority which is currently set out in Schedule A2 - Evaluation Methodology and Criteria.

b) Compliance to any specification and relevant industry standards.

c) Meeting non-financial and/or financial requirements relevant to the products and/or services supplier under the Framework Agreement (as determined the Authority and this tender) and

d) Acceptance of the terms and conditions of the Framework Agreement without negotiation or amendment.

5.8. If the Supplier or new supplier is successful in meeting the requirements set out in paragraph 5.7, then that supplier will be awarded a contract under the Framework Agreement under the Lot in which the Supplier Resilience has occurred and not any other Lot.

SECTION B - Framework Structure & Specific Requirements

1. Lot 1 – Products

Overview

Physiotherapy and Occupational Therapy						
LOT 1						
Acupuncture	Electrotherapy / Ultrasound Therapy	General Exercise Equipment	Hot and Cold Therapy	Massage Products	Posture & Balance	Tapes, Strapping and Associated Products

In each of the sections below we provide an image of the structure, this is to be transparent and show suppliers the variety of products that could be included and when appropriate how we have grouped similar products. N.B. In some cases the end point weights or sizes have been consolidated for the purposes of the image. This is a guide and not intended to be restrictive, if there are products which fall with the parameters of the specification but don't fit, please submit at tender and we will consider for inclusion e.g., an acupuncture needle which has dimensions outside of those listed in level 4 of the image below.

1.1. Acupuncture

Structure Guide

Level 2	Level 3	Level 4
Acupuncture	Needles	0.16 x7mm 0.20x 7mm
		0.18-0.20mm x 13-25mm
		0.25-0.30mm x 25-35mm
		0.25-0.30mm x 40-60mm
		0.25-0.30mm x 70-90mm
		0.35-0.40mm x 25-35mm
		0.35-0.40mm x 40-60mm
		Silver/Gold Needles
	Mini Needles	0.11mm x 0.3mm
		0.15mm x 0.6mm
		0.17mm x 0.9mm
		0.20mm x 1.2mm
		0.20mm x 1.5mm

This section is for Acupuncture products including, but not limited to: Acupuncture Needles – specifically designed for acupuncture and intended for insertion into the skin of the patient to stimulate acupuncture points.

Specific – ADDITIONAL STANDARD AND LEGISLATION	
ISO 17218:2014	Sterile acupuncture needles for single use

Acupuncture needles (including mini needles) must:

- Be made from medical grade stainless steel. (Exception is the gold/silver variants)
- Be available in a range of lengths and thicknesses.
- Packaging must allow access to the product whilst maintaining sterility.

1.2. Electrotherapy / Ultrasound Therapy

Structure Guide

Level 2	Level 3	Level 4
Electrotherapy Equipment	Electrodes	Less than or = to (5cm x 5cm)
		Greater than 5x5cm
	Electo Acupuncture Devices	
	TENS Machine	
	NMES	
	FES	
	Combined TENS / NMES	
	Combined TENS / NMES / FES	
	Electromyography	
	Ultrasound Therapy Devices	
	Laser Therapy	
	Shockwave Therapy Devices	Functional
		Radial
		Combined

This section is for electrotherapy, ultrasound and associated products and accessories designed for use in physiotherapy and occupational therapy, as well as associated accessories including probes, electrodes, and lead wires.

Specific – ADDITIONAL STANDARD AND LEGISLATION	
BS EN 60601-2-10:2015+A1:2016	Requirements for the basic safety and essential performance of nerve and muscle stimulators

Electrotherapy Electrodes includes alternative options e.g., Pads / Belts. They conduct electrons from the electrotherapy device into the patient and serve as a conductor and medium between the two.

These products are intended to provide electrotherapy treatment by the controlled use of electrical energy for a wide range of conditions including pain management and muscle rehabilitation.

All products must;

- Include operating instructions which detail contra-indications and safety considerations.
- When re-usable, be suitable for cleaning with detergent wipes.
- Have replacement accessories available to purchase separately. Please submit via the "product lines" template.

1.3. General Therapy and Exercise

Structure Guide

Level 2	Level 3	Level 4	Level 5
General Exercise Equipment	Gym Balls	Size	
	Inflation Pump		
	Ankle / Wrist Weights	Weights	
	Dumbbells	Weights	
	Kettlebells	Weights	
	Barbells	Bars	
		Collars	
		Fixed Barbells	Weights
		Weight Plates	Weights
	Resistance Bands	Resistance Level	
	Putty	Resistance Level	
	Gel Ball		
	Exercise Bar (Flexible)		
	Lower Limb Exerciser		
	Exercise Mat	Size	
	Dynamometer		
	Goniometer		

This Section is for a full range of general therapy and exercise products intended for use in Physiotherapy and Occupational Therapy centres. These centres are increasingly replicating the commercial gym environment to bridge the gap between health setting and self-care.

- All re-usable products must be suitable for cleaning with standard detergents.
- Where a product has a variety of weights, densities, resistance, or sizes that these varieties are all included in the product submission.
- Ankle / Wrist Weights must include a strap or mechanism to secure the weight to the limb.
- Resistance Bands must be Latex-Free
- Where appropriate Safe Working Loads must be provided, desirable that these are included on the product.

1.4. Temperature Management

Structure Guide

Level 2	Level 3	Level 4	Level 5
Hot and Cold Therapy	Ice Packs	Single Use	Compact (13-15cm x 15-21cm)
			Standard (12-16cm x 22-27cm)
			Large (11-16cm x 28-36cm)
		Re-usable	
	Cool Gel		
	Cold Sprays		
	Cold Compression Wraps	Ankle	
		Knee	
		Shoulder	
		Universal	
		Compression Wrap IcePacks	
	Cryotherapy Cooler and Associated Wraps	Cooler	
		Wraps	ForeFoot
			Ankle
			Calf
			Knee
			Thigh
			Hip
			Back
			Shoulder
			Elbow
			Hand
			Universal
	Heat Packs	Single Use	
		Re-usable	
	Hot / Cold Packs	Compact (3-10cm x 10-15cm)	
		Standard (11-15cm x 25-30cm)	
		Large (10-25cm x 30-50cm)	
	Hot and Cold Product Covers		
	Hot / Cold Compression	Knee	
		Shoulder	

This section includes a variety of Hot and Cold Therapy Products, Heat Therapy improves circulation and helps muscles to relax whereas Cold Therapy reduces inflammation by

decreasing blood flow to the area. These products can be used for a variety of conditions including muscular pain, swelling, aching joints and aid in the post operative recovery phase.

- All re-usable products must be suitable for cleaning with standard detergents.
- All Products must be suitable for disposal in standard non-clinical waste when not contaminated.
- Cold Packs must provide cold relief for at least 20 minutes in a room temperature environment.
- Cold Compression Wraps are independent products which must be re-usable, and any Gel pack versions must be suitable for placing in the freezer
- Hot / Cold Packs – Reusable must be suitable for the freezer and use in a Microwave.
- Cryotherapy Compression Wraps are those that are specifically dependant on a Cryotherapy Cooler. These must be available in a range of sizes and be re-usable.

1.5. Massage Products

Structure Guide

Level 2	Level 3	Level 4
Massage Products	Massage Roller	Mini / Pedi
		Short (30cm long)
		Medium (45cm long)
		Long (90cm long)
	Massage Balls	
	Massage Knuckle	
	Massage Tools	
	Massage Lotion	
	Massage Oil	

This section is for the full range of massage products intended for use in physiotherapy and occupational therapy that enable controlled pressure to be applied to the body of the patient both manually and mechanically.

- For Massage Lotion / Oil products the ingredients must be displayed
- For Massage Lotion / Oil products instructions must be provided which includes a list of contra-indications.
- All re-usable products must be suitable for cleaning with standard detergents.

1.6. Posture & Balance

Structure Guide

Level 2	Level 3
Posture and Balance	Balance Board & Domes
	Posture Mirror

This section is for products intended for use in Physiotherapy and Occupational Therapy used to help patients develop correct posture and balance.

- Must include Safe Working Load details where appropriate, desirable to be clearly identifiable on the product.

1.7. Tapes, Strapping and Associated Accessories

Structure Guide

Level 2	Level 3	Level 4	Level 5
Tapes, Strapping and Associated Products	Kinesiology Tape	2.5cm	
		5cm	
		7.5cm	
		10cm	
	Zinc Oxide Tape	1.25cm	
		2.5cm	
		3.75cm	
		5cm	
	Scissors		
	Pre-Tape Adhesive		
	Adhesive Remover		
	Foam Underwrap	2.5cm	
		5cm	
		7cm	
	Hook and Loop	Self-Adhesive	
		Sew-on	(15-20mm) Width
			(25-30mm) Width
			(50mm) Width

This section is primarily focused on Kinesiology and Sport (Zinc Oxide) style tapes. Kinesiology tape is a thin, stretchy, elastic strip with an adhesive back. Therapeutic kinesiology tape that can benefit a wide variety of musculoskeletal and sports injuries, plus inflammatory conditions.

Kinesiology tape is almost identical to human skin in both thickness and elasticity, which allows kinesiology tape to be worn without binding, constricting or restriction of movement.

2. Lot 2 – Large Therapy Equipment.

Overview

LOT 2		
CPM Machines (Continous Passive Motion)	Large Exercise Machines / Equipment	Robotic Therapy

Products listed in Lot 2 have a very low turnover, customer engagement has identified a need for the products to be available for purchase however the features and attributes required are not standardised. Customers will be provided a list of suppliers and products available through the framework.

Once a customer is ready, we will then list the product on framework for purchase via the transacted route.

2.1. CPM Machines

This section covers **passive** therapy devices, namely CPM machines. The equipment that a person may use to help with recovery after undergoing joint surgery. The idea behind CPM machines is that they increase range of motion. They provide sessions of continuous motion for joints that a person is unable to move freely. People may experience pain when trying to move their joint after undergoing surgery. This can cause them to avoid moving the joint, which can result in stiffness, a loss of motion, and the development of scar tissue.

2.2. Large Exercise Machines / Equipment

This section covers **active** therapy devices, with the shift for physiotherapy rehabilitation to bridge the gap between Hospital care and Self Care, moving treatment from passive therapy to active therapy these centres are increasingly replicating the commercial gym environment to help educate and remove perceptions that patients often have around attending gyms.

The equipment considered for this section includes but is not limited to, treadmills, exercise bikes, elliptical trainers, rowers, squat racks and smiths machines.

2.3. Robotic Therapy

Robotic technology is developing rapidly within the Physiotherapy discipline, whilst we believe that this technology will be transformational to the NHS in the future, we are looking to connect with suppliers who are starting to offer the technology to the public sector.

We are excluding full exoskeleton units as we believe the funding for these devices will be via other procurement routes.

This section includes robotic assistive therapy equipment which can be used on the lower limb or upper limb.