Key Issues

- EU Exit

- AAR: CtE, Horizon Scanning, Tariff

- Trade

- Regulatory: New MDR

- Procurement

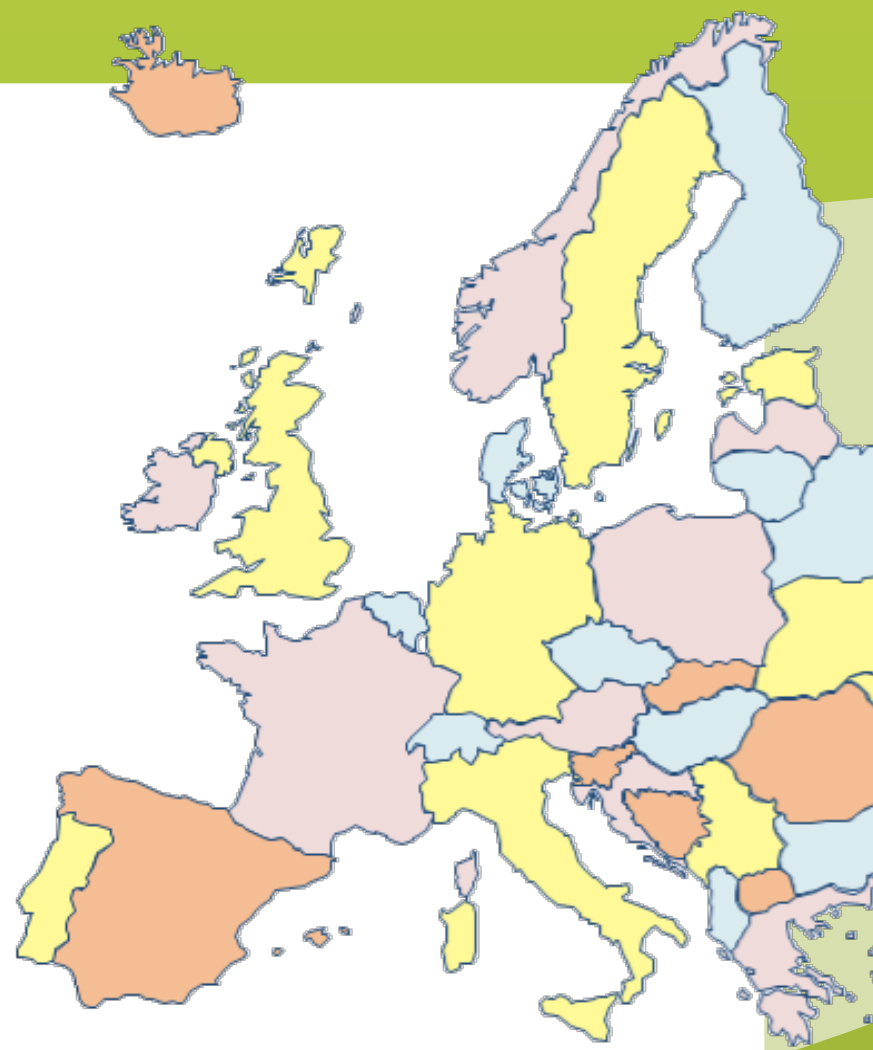- Ethics and Compliance

EU Exit

- **Concerns**
  - Research & Development
  - People and skills
  - Intellectual Property
  - Regulation
  - Procurement

- **Opportunities**
  - Manufacturing
  - Growth of SMEs
  - Wider health system collaboration

AAR: Aspirations & Expectations

- **New Managed Access Pathway for Medtech**
  - Rigorous selection criteria and a select few getting full support

- **Systematic Horizon Scanning**

- **Digital program for NICE and MHRA**

- **Reimbursement flexibilities….but no significant change to tariff**

- **Better access to a "mandated" NICE program for Medtech**

- **National Innovation Partnership and Innovation Exchanges will go ahead**

- **Rationalise AHSNs – remit/process (and numbers?)**

- **Continue role of "Coverage with Evidence development" (CtE)**

Trade

- UK based SMEs looking for growth

- US – major market, good infrastructure and commercial environment

- China and (lesser extent) India – growth and growth

- Middle East/Asia

Medical Device Regulation

- **Increased scrutiny**
  - Notified Body accreditations and audit requirements
  - Greater clinical performance compliance requirements
  - Higher Risk products through 'scrutiny procedure'
  - Post Market Surveillance and vigilance enhancements
  - Increased use of EUDAMED: transparency of appropriate product data

- **Estimated Timings**
  - To be published in the 'Official Journal', April 2017
  - 3yr Transition Period to end April 2020 (IVDs April 2022)
  - Implementing & Delegating Acts to be developed during Transition Period

Procurement

Cost effectiveness   Cost containment

- **Short Term**
  - Greater transparency & price benchmarking
  - More control, coordination and focus
  - Clinical standardisation & product rationalisation
  - Transition to a new central purchasing model
  - Drive towards eProcurement
  - A distinction between "high value" items and commodity

- **Medium/Long Term Outlook**
  - Innovation pull: less tactical more strategic approach to innovation
  - Clinical standardisation
  - Centres of excellence
  - Different industry business models

Initiatives
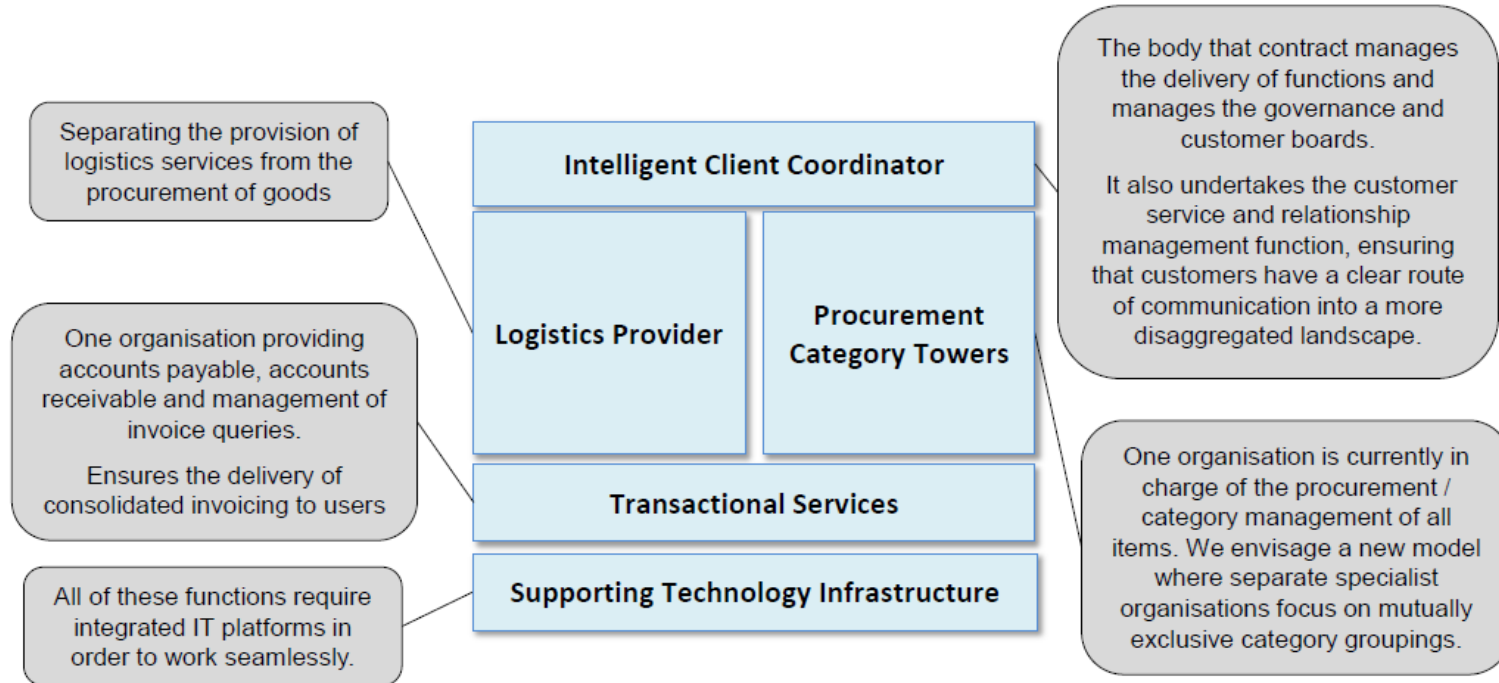
- **Carter Report**
  - Improve data: GS1 standards, national catalogues
  - Demand aggregation
  - National category strategies: built on "Getting it Right First Time"
  - Core List
  - Clinical Evaluation Team

- **DH Future Operating Model**
  - 11 Category Towers: experts procurement service providers
  - Single logistics supplier
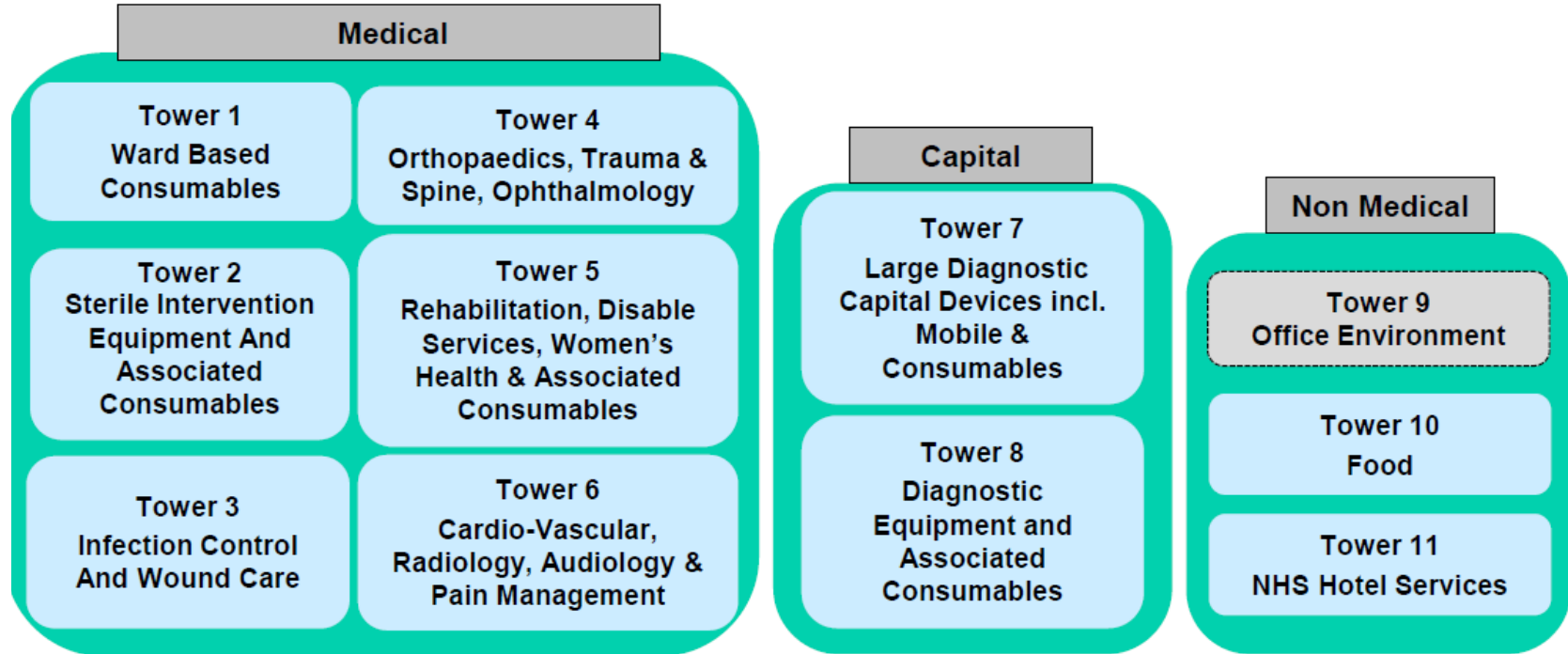 - Heavier client Function (inc NHS customer development)

Future Operating Model

Separating the provision of logistics services from the procurement of goods

Intelligent Client Coordinator

The body that contract manages the delivery of functions and manages the governance and customer boards.

It also undertakes the customer service and relationship management function, ensuring that customers have a clear route of communication into a more disaggregated landscape.

Logistics Provider

Procurement Category Towers

One organisation providing accounts payable, accounts receivable and management of invoice queries.

Ensures the delivery of consolidated invoicing to users

Transactional Services

Supporting Technology Infrastructure

All of these functions require integrated IT platforms in order to work seamlessly.

One organisation is currently in charge of the procurement / category management of all items. We envisage a new model where separate specialist organisations focus on mutually exclusive category groupings.

This would all be seamless from a client perspective, with items purchased through a NHS Catalogue

Category Towers

Medical

Tower 1
Ward Based Consumables

Tower 4
Orthopaedics, Trauma & Spine, Ophthalmology

Tower 2
Sterile Intervention Equipment And Associated Consumables

Tower 5
Rehabilitation, Disable Services, Women's Health & Associated Consumables

Tower 3
Infection Control And Wound Care

Tower 6
Cardio-Vascular, Radiology, Audiology & Pain Management

Capital

Tower 7
Large Diagnostic Capital Devices incl. Mobile & Consumables

Tower 8
Diagnostic Equipment and Associated Consumables

Non Medical

Tower 9
Office Environment

Tower 10
Food

Tower 11
NHS Hotel Services

(More) Initiatives

- **Clinical Evaluation Team**
  - Clinical effectiveness of everyday healthcare consumables
  - Anticipate linked procurement activity

Work plan June - November 2016
Fast Track Pilot Project
IV Luer slip syringes
Primary Projects
Suction tubing
Urine drainage bags - non sterile
Blunt fill needles
Examination gloves - non sterile
Skin barrier films
Gelling fibre dressings
Secondary Projects
Examination gloves – sterile
ECG electrodes – diagnostic
ECG electrodes - monitoring
Single use tourniquets
Blunt fill filter needles
Urine drainage bags - sterile
Dressings – Film, adhesive tape
Plugs, Stoppers & Bungs
Suction catheters

Product categories identified for future review
IV therapy consumables
e.g. cannula, lines, administration sets, needle free connectors, dressings
Wound care and dressings
e.g. post-op dressings, foams, bandages, non-adherent super absorbents
Clinical waste products
e.g. clinical waste containers and bags
Diagnostic consumables
e.g. specimen containers, safety lancets
Oxygen therapy
e.g. tubing, masks, nebulisers, valves, bag-valve masks
Wipes
e.g. patient dry, wet, skin and environmental
Patient hygiene requisites
e.g. razors, toothbrushes, shower gels
Medical packs
e.g. wound care, catheterisation, cannulation
Medical pulp
e.g. trays, bowls, bedpans and urinals

High Cost Devices

- **Move High Cost Devices (as defined in tariff) used within Specialised Services to a "zero cost" model**
  - Announced in commissioning intentions 16/17
  - Mandated procurement route for NHS Trusts

- **Total spend on HCD is £450m – £500m (Drugs £2bn)**

- **Centralised procurement via NHS Supply Chain**

- **Future phases will address clinical standardisation and product rationalisation**

Industry/HCP Interaction

- **Changes to Industry Code of Conduct**
  - No direct sponsorship of Healthcare Professionals
  - Educational Grants to go via a third party

- **NHS England working on Conflicts of Interest**
  - Includes HCP/Industry interactions: Hospitality, payments etc
  - Framework for identification and management of CoI
  - Increased disclosure

- **"Credentialing" of Medtech staff at trust level**
  - Fragmented approach at local level
  - Working with NHS England on a national scheme

Strategic Work Streams

"Industry Forward View"

Supporting execution of vision in 5 Year Forward View through a consistent system for the nurturing and spread of innovation

Company Growth

Support to grow competitive companies through the right economic initiatives and development of skills

Value not Price

Deliver improved NHS efficiency by driving uptake of value-add solutions along guided runway encompassing payment, incentives and procurement

Patient Centricity

Create partnerships and advocacy for patient led pathways and standards to reduce variation in outcomes

Digital

Mechanisms to segment, promote and scale up digital solutions that support outcomes and efficiency

System Leadership

Develop and implement a strategic plan to engage with and influence new and emerging forms of local system leadership and models of care

Reputation

Enhanced regulatory and compliance systems consistently implemented across industry and recognised by the health system to build trust and cooperation