INNOVATION IS GREAT BRITAIN

Your Access Guide to the NHS

The Current Market

The UK medical device market was valued at GBP£6,899.8mn (US$11,315.6mn) in 2014. This makes it the third largest market in Europe, behind Germany and France and the sixth largest in the world, representing 3.3% of global spending on medical devices. Per capita spending is amongst the world's top 20 at GBP£108.7 (US$178.2). The UK spent 4.6% of total health expenditure and 0.4% of GDP on medical devices in 2014.

It is estimated that the market grew by 5.0% in 2014. Other medical devices is the largest product area accounting for 26.4% of the total market in 2014, followed by consumables with a 23.3% share and diagnostic imaging with a 17.9% share.

The market remains heavily reliant on imports in most sectors, as local manufacturing capacity is more geared to exports. The UK has few large medical device manufacturers and over three-quarters of the market is therefore supplied by imports, a percentage which rising demand has boosted in recent years.

The market was valued at US$11.3bn in 2014. Medical device imports supply around 76% of the market and were valued at US$8.9bn in 2014. The UK is a significant global exporter of medical devices and remains among the world's top 10.

In 2014, according to latest published data from Eurostat, the UK produced medical devices worth EUR4.0bn (US$5.3bn) with particular strengths in bandages & dressings, electrodiagnostic apparatus, orthopaedics & prosthetics and other medical devices. Production figures are under-reported, BMI estimates medical device output to exceed US$8.0bn.

The UK is the most attractive market in Western Europe (WE) in which to commercialise a medical device according to BMI's Medical Device Risk/Reward Index (RRI).

The UK market is dominated by the National Health Service (NHS), which accounts for over 80% of expenditure. Long term public investment projects generally continue to be funded under Private Finance Initiative (PFI) schemes. The private sector remains small - if well equipped - and largely based in England. There are noticeably lower levels of private spending in Scotland and Wales.

Healthcare System

In the UK, the majority of healthcare is provided by the National Health Service (NHS). With the exception of charges for some prescriptions and optical and dental services, the NHS remains free at the point of use for anyone who is a resident in the UK.

Although funded centrally from national taxation, NHS services in England, Scotland, Wales and Northern Ireland are managed separately. They are similar in most respects but there are some significant differences.

For example, prescription charges have been abolished in Wales, Scotland and Northern Ireland, but residents in England still have to pay. The NHS in England is controlled by the UK government through the Department of Health.

The Department of Health has responsibility for government policy for health and social care matters and for overseeing the National Health Service (NHS) in England, whilst responsibility for the NHS in other parts of the UK has been devolved to the Scottish, Welsh and Northern Irish governments.

The Conservative government elected in May 2015 has promised a minimum real terms increase in NHS funding in England over the next five years to meet the needs of the Five Year Forward Review drawn up in 2014 by NHS England.

The Review identified the need for an extra GBP£30bn (US$45.5bn) a year in funding by the end of the decade.

Around GBP£22bn (US$33.3bn) of this target will come from efficiency savings including GP practices offering some hospital services, such as minor surgeries or scans.

In FY 2015-16, NHS England plans to make available an extra GBP£2.0bn (US$3.0bn) for frontline services, helping to kick start the investment needed to create new care models and further invest in primary care. The devolved administrations in Scotland, Wales and Northern Ireland will also receive extra funding.

Despite the increase in funding, the focus remains on creating efficiency saving. The reorganisation of the NHS under the Health & Social Care Act 2012 has a seen a structural shift, with Primary Care Trusts being abolished and replaced by Clinical Commissioning Groups and the establishment of NHS England in April 2013.

The different supply chains this has created and also the focus on efficiency savings under initiatives such as the Quality, Innovation, Productivity and Prevention (QIPP) means industry players have had to adapt the way they do business with the NHS. For example, the Department of Health is encouraging NHS trusts to use GS1 bar-coding, a system that makes it easier.

Future Performance Levels 2014-2019

An improved performance for the medical device market is expected over the next five years. In local currency terms for 2014-2019 a CAGR of 3.8%, higher than the 1.0% CAGR for the 2009-2014 period is expected.

This reflects higher economic growth over the forecast period, for which an average 2.5% rise in real GDP through to 2019 is forecast. Patient aids will have the highest growth during this period with a 2014-2019 CAGR of 5.0% in local currency terms, followed by diagnostic imaging (4.4%), orthopaedics & prosthetics (4.0%) and consumables (3.8%).

Dental products and other medical devices will have below average growth during the 2014-2019 period with a CAGR of 2.8%.

In US dollar terms, the 2014-2019 CAGR will be higher at 5.1%, which will see the market grow from US$11,315.6mn in 2014 to US$14,538.5mn in 2019.

It is forecast that the consumables market will grow at a CAGR of 3.8% in local currency terms for the 2014-2019 period, in line with overall growth in the medical device market. This compares to a CAGR of 1.6% for the 2009-2014 period and reflects higher economic growth over the forecast period, although annual growth rates will be lower than the 8.1% rise achieved in 2014, due to efficiency measures and pricing pressures.

It is forecast that the market will grow at a US dollar 2014-2019 CAGR of 5.2% taking the value from US$2,639.8mn in 2014 to US$3,396.2mn in 2019.

Imports of consumables amounted to GB£1,285.1mn (US$2,107.5mn) in 2014, equal to 23.8% of the total, making this the second largest import area.

Syringes, needles & catheters were the largest subcategory, followed by bandages & dressings, other consumables and suturing materials. Consumable imports have seen below average growth for the medical device sector over the past five years, expanding at a 2009-2014 CAGR of 1.3% in local currency terms and 2.4% in US dollar terms.

Suturing materials was the fastest growing subcategory during this period, while syringes, needles and catheters was the slowest. In 2014, imports grew by 10.2% in local currency terms and by 16.6% in US dollar terms.

Exports of consumables amounted to GBP£1,008.5mn (US$1,654.0mn) in 2014, equal to 25.4% of the total, making this the largest export area. Bandages & dressings were the largest subcategory, followed by syringes, needles & catheters, suturing materials and other consumables.

Consumable exports have seen above average growth for the medical device sector over the past five years, expanding at a 2009-2014 CAGR of 2.5% in local currency terms and 3.7% in US dollar terms.

Suturing materials was the best performing subcategory during this period, while other consumables was the weakest. In 2014, exports grew by 0.4% in local currency terms and by 6.2% in US dollar terms.

Diagnostic

It is forecast that the diagnostic imaging market will grow at a CAGR of 4.4% in local currency terms for the 2014-2019 period, which is above average for the medical device market.

This compares to a CAGR of just 1.3% for the 2009-2014 period, which included contractions in 2011 and 2014. It is forecast that the market will grow at a US dollar 2014-2019 CAGR of 5.8% taking the value from US$2,020.3mn in 2014 to US$2,673.7mn in 2019.

Diagnostic imaging imports totalled GBP£796.0mn (US$1,305.5mn) in 2014, equal to 14.7% of the total. Electrodiagnostic apparatus was the largest subcategory followed by imaging parts & accessories and radiation apparatus. Diagnostic imaging has been one of the strongest import product areas over the past five years growing at a 2009-2014 CAGR of 2.5% in local currency terms and 3.7% in US dollar terms.

Diagnostic imaging exports totalled GBP£986.2mn (US$1,617.3mn) in 2014, equal to 24.9% of the total. Electrodiagnostic apparatus was the largest subcategory followed by radiation apparatus and imaging parts & accessories. Diagnostic imaging has been the strongest export product area over the past five years.

Dental

It is forecast that the dental products market will grow at a CAGR of 2.8% in local currency terms for the 2014-2019 period, making it one of the slowest growing sectors of the medical device market.

This compares to a CAGR of 2.3% for the 2009-2014 period and reflects higher economic growth over the forecast period.

It is forecast that the market will grow at a US dollar 2014-2019 CAGR of 4.1% taking the value from US$713.7mn in 2014 to US$872.9mn in 2019.

Imports of dental products were valued at GBP£226.2mn (US$371.0mn) in 2014, equal to 4.2% of the total. Instruments & supplies account for over 85% of import activity. Between 2009 and 2014, imports of dental products grew at a CAGR of 2.1% in local currency terms and 3.3% in US dollar terms, which was above average for the medical device sector.

Exports of dental products were valued at GDP£118.9mn (US$195.1mn) in 2014, equal to 3.0% of the total. Instruments & supplies account for around 90% of export activity. Between 2009 and 2014, exports of dental products grew at a CAGR of 4.0% in local currency terms and 5.2% in US dollar terms, which was above average for the medical device sector.

Orthopaedic

It is forecast that the orthopaedics & prosthetics market will grow at a CAGR of 4.0% in local currency terms for the 2014-2019 period. Growth will be slightly above average for the medical device market. This compares to a CAGR of 4.4% for the 2009-2014 period.

The sector will benefit from higher economic growth and the steadily expanding elderly population, but growth rates will be constrained by pricing pressures and a slowdown in artificial joint procedures. It is forecast that the market will grow at a US dollar 2014-2019 CAGR of 5.3% taking the value from US$1,276.8mn in 2014 to US$1,654.2mn in 2019.

Imports of orthopaedics & prosthetics reached GBP£650.1mn (US$1,066.2mn) in 2014, equal to 12.0% of total medical device imports. Artificial joints were the largest subcategory followed by fixation devices and other artificial body parts. Between 2009 and 2014, imports of orthopaedics & prosthetics grew at a CAGR of 7.0% in local currency terms and by 8.2% in US dollar terms, making this the fastest growing product area of the medical device sector, despite a negative CAGR for fixation devices.

Exports of orthopaedics & prosthetics reached GBP£418.5mn (US$686.3mn) in 2014, equal to 10.6% of total medical device exports.

Artificial joints were the largest subcategory followed by other artificial body parts and fixation devices. Between 2009 and 2014, exports of orthopaedics & prosthetics grew at a CAGR of -0.8% in local currency terms and by 0.4% in US dollar terms. The below average performance reflects a drop in exports of artificial joints.

Patient Aids

It is forecast that the patient aids market will grow at a CAGR of 5.0% in local currency terms for the 2014-2019 period. Growth will be above average for the medical device market. This compares to a CAGR of 0.5% for the 2009-2014 period and reflects higher economic growth over the forecast period and the increasing healthcare needs of the expanding elderly population.

It is forecast that the market will grow at a US dollar 2014-2019 CAGR of 6.4% taking the value from US$1,678.2mn in 2014 to US$2,289.8mn in 2019.

Imports of patient aids amounted to GBP£950.4mn (US$1,558.6mn) in 2014, equal to 17.6% of the total.

Portable aids account for around three-quarters of import activity. Between 2009 and 2014, imports of patient aids grew at a low CAGR of 0.7% in local currency terms and 1.9% in US dollar terms, which was below average for the medical device sector.

This was largely due to a negative CAGR for pacemakers, other portable aids and therapeutic respiration apparatus. Hearing aids were by far the most dynamic product group during this period.

Exports of patient aids amounted to GBP£459.2mn (US$753.1mn) in 2014, equal to 11.6% of the total. Portable aids account for around two-third of export activity. Patient aids have been the weakest export product area recording a 2009-2014 CAGR of -7.2% in local currency terms and -6.1% in US dollar terms. Hearing aids and pacemakers were the only product groups to make gains during this period.

Other Medical Devices

Other medical devices are the largest import area with imports of GBP£1,501.2mn (US$2,462.0mn) in 2014, accounting for 27.8% of total medical device imports.

The largest identifiable subcategories in medical devices have underperformed over the past five years, recording a 2009-2014 CAGR of -0.8% in local currency terms and 0.3% in US dollar terms, despite double-digit growth for blood pressure monitors, manual wheelchairs and ophthalmic instruments. In 2014, the overall performance was stronger with a rise of 5.2% in local currency terms and 11.3% in US dollar terms. By subcategory the performance was very mixed with UV/IR apparatus, dialysis apparatus and transfusion apparatus posting negative growth, while ophthalmic instruments and hospital furniture achieved rises in excess of 20%.

Accessing the NHS

Key NHS Facts

- The NHS is the fifth largest employer in the world with 1.3 million employees in 2014
- The NHS delivers over 80% of the UK's healthcare provision
- The NHS operates through different models in the UK under NHS Scotland, NHS Wales, NHS Northern Ireland and NHS England

NHS England:

- Over 200 Clinical Commissioning Groups (CCGs)
- 156 acute trusts (including 100 foundation trusts)
- 56 mental health trusts (including 42 foundation trusts)
- 34 community providers (15 NHS trusts, 3 foundation trusts and 16 social enterprises)
- 10 ambulance trusts (including 5 foundation trusts)
- c.8,000 GP practices
- 853 for-profit and not-for-profit independent sector organisations, providing care to NHS patients from 7,331 locations
- 15 Academic Health Science Networks (AHSNs)/6 Academic Health Science Centres

Procurement and Routes to Market (NHS England)

The NHS spends over £25 billion every year on goods and services. Effective management of this resource is vital, at a time when demand is growing due to an ageing population and patients living longer because of better treatments.

"Better Procurement, Better Value, Better Care", a procurement development programme for NHS England, was published on 5 August 2013 and sets the procurement direction of travel for NHS organisations.

In real terms this means trusts need to find over £1.5 billion of procurement efficiencies.
There is also a projected annual budget gap of £30 billion by 2020/21 which is driving the need to make efficiencies across the board.
Recommendations for efficiencies in procurement (and other operational areas) were set out in Lord Carter's Review of Operational Productivity in NHS Providers, published in June 2015.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/434202/carter-interim-report.pdf

The Department of Health strategy is to build a modern, effective and efficient procurement capability that is among the best in the world – one that truly delivers taxpayer value, supports innovation, stimulates growth, and most importantly, delivers the highest quality patient care.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226835/procurement_development_programme_for_NHS.pdf

Currently there are many different ways of supplying products and services to the NHS – none of which are mandated. NHS organisations can buy from many sources, within the EU Procurement Regulations, national and local procurement policies. NHS organisations in England try to make the most effective use of their resources by getting the best possible value for money when purchasing via any of the routes explained in this document, and will be focused on meeting the targets outlined in the NHS England Business Plan. This is part of the NHS England 5 Year Forward View document issued in October 2014, a copy of which can be found on:
http://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf

Accessing the NHS

For general information there is a Department of Health Procurement website.
https://www.gov.uk/government/organisations/department-of-health/about/procurement

There are five main routes to market for companies interested in supplying the NHS:

1a) Selling Direct to Trusts
1b) Primary Care

2. Selling Through NHS Supply Chain (NHSSC)

3. Selling Through Collaborative Purchasing Arrangements

4. National Framework Collaborations and Contracts

5. Government Tenders and Contracts

1(a). Selling Direct to Trusts

A company which has a specific product or service that can be easily matched to an NHS organisation can use this process to sell directly to the healthcare service provider of their choice. This will involve identifying the right person/people (generally clinicians, the procurement team and the finance team) within the selected NHS organisation to deal with.

Service providers, who include all Trusts, make their own purchasing decisions and can purchase directly from the manufacturer or distributor within purchasing rules and arrangements.
www.nhs.uk/NHSEngland/aboutnhs/Pages/authoritiesandtrusts.aspx

Advantages

- A smaller number of tenders to compete against
- Better awareness of Trusts' needs makes it easier to supply the right products and services
- Direct involvement of clinicians in purchasing
- Encourages innovation and support for R&D in emerging treatments.

Challenges

- Identifying the right buyer and decision makers is more challenging here than other routes
- This route is fragmented, as each Trust may operate differently and there are hundreds of them.

Accessing the NHS

1(b). Primary Care

If a device is to be prescribed in a primary care setting, e.g. by a family doctor (GP), an application should be made to the NHS Business Services Authority to have the product included and reimbursed through part IX of the Drug Tariff.
http://www.nhsbsa.nhs.uk/PrescriptionServices/3399.aspx

2. Selling Through NHS Supply Chain (NHSSC)

The NHS Supply Chain, which is currently operated by DHL, attempts to provide an innovative and dedicated end-to-end supply chain service that meets the needs of every NHS healthcare organisation in England. Through its suite of world-class logistics, procurement and customer-support services, NHS Supply Chain aims to provide over £1 billion of savings to the NHS over the next 5 years, enabling customers to release the resources they need to focus actively on in the delivery of quality frontline patient care and cost-base management.
www.supplychain.nhs.uk

Advantages

- A great visible and accessible catalogue for companies to promote their products and services
- The database sits at the heart of the NHS – all NHS buyers have access
- Quick and easy for a company to set themselves up on this system.

Challenges

- Highly competitive, with lots of companies and hundreds of thousands of products, so companies need to ensure their products stand out
- All contracts go through an extensive tender process.

Other websites supplying healthcare supplies include Bunzl Healthcare and Squadron Medical.

3. Selling Through Collaborative Purchasing Arrangements

Local NHS organisations may choose to work together in a local purchasing arrangement, in order to benefit from the economies of scale that bulk buying can support and to avoid duplication of work, including product assessments. These collaborative purchasing arrangements were aligned originally to 10 strategic health authorities. Today, these partnerships in both the public and private sectors collaborate to make the most effective procurement and supply-chain decisions in order
to provide best value for their stakeholders.

http://www.commercialsolutions-sec.nhs.uk/
http://www.noecpc.nhs.uk
www.eoecph.nhs.uk
www.lpp.nhs.uk
http://www.sbs.nhs.uk/procurement
http://www.healthtrusteurope.com/

There are also procurement 'alliances and confederations' which have been running for a number of years to encourage trusts to collaborate over their requirements e.g.
http://www.ppsa.nhs.uk/
http://shelfordgroup.org/

Accessing the NHS

Advantages
- Allows suppliers to hit a number of trusts (Acute and CCGs) in one go
- Stronger partnerships with suppliers through commitment to contracts.

Challenges
- Individual Trusts retain the responsibility for contractual sign off
- Not all individual Trusts within the group will have budget to spend or the same level of interest in the product.

4. National Framework Collaborations and Contracts

These are collaborative purchasing contracts which comprise groups of suppliers who have responded to tender notices and have had their credentials reviewed and approved. Such companies then contractually agree to provide a certain product or service at a given price to any NHS trust that uses them.

The Crown Commercial Service lead on these and their role is to provide procurement savings for government and the UK public sector, including health, but also local government, devolved administrations, education and not for profit organisations.
http://ccs.cabinetoffice.gov.uk

There is a specific section for suppliers:
http://ccs.cabinetoffice.gov.uk/i-am-supplier

Advantages
- First stage of tender work is completed only once
- Suppliers' credentials are then held on a database which NHS buyers can use as a reference for new suppliers
- Can help a new supplier understand the market and gain visibility in the NHS.

Challenges
- No commitment is given for volume of business
- Companies will still have to undertake final local procurement paperwork
- Not every product category has a national framework.

5. Government Tenders and Contracts

The level of spend can determine the method of contract advertising and what process may be followed

The NHS must advertise all large-scale contracts with a total value of over 134,000 to 207,000 Euros (£111,676-£172,514)* (for supplies and services) or £4,332,012/5,186,000 Euros* (for works) in the Supplement to the Official Journals of the European Union (OJEU), which is issued daily and is a good place to see who is buying what.

For a fee, a number of commercial organisations will search OJEU and provide regular lists of contracts which may be of interest.
www.ted.europa.eu

Accessing the NHS

A new EU Directive on public procurement came into force in April 2014 setting new rules for public bodies when purchasing goods and services, including clinical services. EU member states have up to 2 years to implement the Directive.
http://www.nhsconfed.org/resources/2013/09/new-eu-directive-on-public-procurement

Advantages

- A very simple and effective way to see which companies have won tenders and who is buying what
- This can give companies a real advantage if they consult this database regularly to see who is buying large scale equipment.

Challenges

- All suppliers use this route, so there is high competition
- Can be a lengthy process.

Every NHS organisation has been asked to use Contracts Finder, which lets you search for information about contracts worth over £10,000 with the government and its agencies. You can use Contracts Finder to search for current contract opportunities, find out what's coming up in the future and look up details of previous tenders and contracts.
https://www.gov.uk/contracts-finder

To complement this sid4gov has been developed by Crown Commercial Service to provide a replacement for sid4health and the supply2health register of suppliers.
https://sid4gov.cabinetoffice.gov.uk.

The future vision is to create a single supplier registration portal that will provide one place for suppliers to register and provide information for procurement in support of management tenders across the public sector. This portal will also provide public sector buyers with a single place to access supplier related information in support of market engagement and procurement processes.

Multiquote is a pricing and sourcing service that is used extensively throughout the Public Sector in the UK and increasingly by NHS trusts. Buyers use the service to enable them to buy at the best prices, find new supplier and provide opportunities to local SMEs.
http://www.multiquote.com

Accessing the NHS

Devolved Administrations: Scotland, Wales and Northern Ireland

The NHS in Scotland

- 14 Territorial Health Boards
- Supported by 7 'Special' Health Boards – provide overarching support to the other boards
- 32 Health and Social Care partnerships – jointly run by NHS and local authority
- 300 Hospitals
- C. 1000 GP practices

All contracts / tenders are published on the Public Contracts Scotland website.
http://www.publiccontractsscotland.gov.uk/

NHS Scotland Procurement

There is a specific division of NHS Scotland which deals with National procurement contracts and they have their own website with advice for potential suppliers.
http://www.nhsscotlandprocurement.scot.nhs.uk

NHS Scotland Innovation

The NHS in Scotland positively encourages innovation and several of the Health Boards have areas of their websites for potential suppliers of innovative products or services to submit ideas for consideration.

However, there is also a National Innovation Assessment portal where individuals or companies can submit ideas for review by a panel of experts. This can support the trialling of new products and assist suppliers with gathering useful data on the use of their products.
https://www.hiap-scotland.org/Home/Index

The NHS in Wales

In addition to national bodies (Crown Commercial Services and NHS Supply Chain), NHS Wales uses regional bodies to carry out the annual 2 billion pounds plus worth of procurement activities for the seven local health boards and three trusts operating in Wales.

Formed in 2011, **NHS Wales Shared Services Partnership Procurement** is the procurement service provider to NHS Wales
http://www.procurement.wales.nhs.uk/index.

E-tendering opportunities can be viewed here:
https://etenderwales.bravosolution.co.uk/nhs/

The **Sell2Wales** website is an information source and procurement portal via which billions of pounds worth of contracts are offered by a wide range of publicly-funded organisations, including NHS Wales, each year. Information on how businesses can promote their services and find contract opportunities is available at
http://www.sell2wales.gov.uk/

Accessing the NHS

The NHS in Northern Ireland

Northern Ireland operates a unique fully integrated Health and Social Care service, providing both primary and secondary care across the region. It is administered locally by the Department of Health, Social Services and Public Safety for Northern Ireland, with operational delivery being the responsibility of the Health and Social Care Board.

Procurement Policy in Northern Ireland

The Procurement and Logistics Service, commonly known as PaLS, is the sole provider of professional supplies services (logistics and procurement) to all public Health and Social Care organisations in Northern Ireland and manages the procurement of goods and services for Northern Ireland health and care bodies, e.g. Trusts, Board and Agencies.

Websites for these organisations can be found at: www.hscni.net. PaLS has an operating budget of about £11m per annum.

PaLS influences over £505m of goods and services spend per annum on behalf of Health and Social Care and operates on a service and budget agreement basis (SLA) with all of its customers. E-tendering opportunities can be viewed at the following link: http://etendersni.gov.uk/

The Role of Academic Health Science Networks (AHSNs) for Suppliers to the NHS in England

In May 2013, 15 Academic Health Science Networks were formed in England to bring together academia, research organisations, local health industries and the NHS to take the lead in their local areas to support innovation in order to meet the health priorities of their population. They have produced a guide to their individual and cross-organisation priority areas. The North West Coast AHSN is the lead on procurement: http://www.ahsnnetwork.com/resources/

The AHSN role, as set out in the Five Year Forward View document issued by the NHS in October 2014 (see below), is to encourage the faster adoption of innovation. Although they cannot buy supplies on behalf of the local NHS organisations, or recommend any individual supplier, they are regarded as key influencers. http://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf

Notes

Notes

THAT'S GREAT BRITAIN

Published November 2015
Information Source: UK Medical Devices Report, Q42015, BMI Research – A FitchGroup Company Incorporating Espicom

For further information contact the UKTI Life Sciences Organisation (LSO) at:
Tel: +44 (0) 20 7333 5442
Web: www.gov.uk/ukti/lso
@UKTI_LSO