

Business opportunities for medical device companies in the UK



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FIME 19th July 2018

Opportunities in the UK market

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- Links



UK

- **UK Population 65 million**
 - England 55 million
 - Wales 3 million
 - Scotland 5.3 million
 - Northern Ireland 1.8 million

- The UK population is projected to continue growing, reaching over **74 million by 2039**. The population in the UK is getting older with 18% aged 65 and over and 2.4% aged 85 and over. In 2016 there were **285 people** aged 65 and over for every 1,000 people aged 16 to 64 years (“traditional working age”).

Opportunities in the UK market

- The medical device trade is import-led, as most domestically manufactured products are exported to other markets. With a consistent demand for imported products, the industry--as well as the regulatory system--is receptive to novel and innovative technologies.
- The language also makes it an easier country to approach for exporters based in English-speaking countries.

How the UK Compares to other markets

	United Kingdom	Compare to FRANCE	Compare to GERMANY
Population	64,088,222	66,553,766	80,854,408
Primary language(s)	English	French	German
Total healthcare spending	\$252 billion	\$330 billion	\$437 billion
Healthcare expenditures total (% of GDP)	9.1%	11.5%	11.3%
Healthcare expenditures per capita	\$3935 (USD)	\$4959 (USD)	\$5411 (USD)
Expenditures on healthcare	Government: 83% Private: 17%	Government: 78% Private: 22%	Government: 77% Private: 23%
Size of medical device market (USD)	\$9.5 billion (USD)	\$14.5 billion (USD)	\$26 billion (USD – 2014)
Number of hospital beds	2.9 per 1000 people	6.4 per 1000 people	8.2 per 1000 people
Age distribution	0-14 years: 17% 15-64 years: 65% 65 years and over: 18% (2015 est.)	0-14 years: 19% 15-64 years: 72% 65 years and over: 19% (2015 est.)	0-14 years: 13% 15-64 years: 66% 65 years and over: 21% (2015 est.)
Life expectancy at birth	Male: 78 years Female: 83 years	Male: 78 years Female: 85 years	Male: 78 years Female: 83 years
Currency	Pound sterling (£)	Euro (€)	Euro (€)

Chart - 2018 EMERGO



United Kingdom medical device industry

- The UK medical device market is the third largest in Europe, behind Germany and France, and the sixth largest in the world. It was valued at \$9.5 billion in 2015.
- Domestic device manufacturing is characterized by a large number of small scale medical device companies alongside a few global manufacturers with a significant presence in the market. Many large US companies operate subsidiaries in the UK. In 2015, there were approximately 3000 medical manufacturers in the UK. The strength of UK manufacturers lies especially in orthopedics but also in imaging, diagnostics, and cardiovascular devices.

UK Landscape

NHS

- England
- Scotland
- Wales
- Northern Ireland



Private Sector

Insurance

- BUPA
- Prudential (PruHealth)
- Aviva
- AXA PPP
- Simply Health
- General Medical
- WPA
- Saga

Private Hospitals

- BMI Healthcare,
- Nuffield Health,
- Spire Healthcare
- Ramsay Health Care
- Aspen Healthcare
- CircleHealth

NHS Facts

- The NHS in England treats more than 1.4 million patients every 24 hours.
- The NHS is one of the largest employers in the world, along with the Chinese People's Liberation Army, the Indian railways and the Wal-Mart supermarket chain.
- The NHS in England is expected to spend £126 billion in 2018/19
- There are more than 7,400 GP practices in England
- In March 2017, the NHS employed 106,430 doctors, 285,893 nurses and health visitors, 21,597 midwives, 132,673 scientific, therapeutic and technical staff (across England's hospital and community healthcare services (full-time equivalent))
- There were 16 million total hospital admissions in England in 2015/16, 28 per cent more than a decade earlier
- The total annual attendances at England's accident and emergency departments was 23 million in 2016/17, 23.5 per cent higher than a decade earlier

Selling into the NHS



- As the biggest healthcare delivery organization in the world, the NHS presents a big opportunity for businesses offering innovative health and care products and services. By the same token, selling into the NHS comes with its own set of challenges
- You need to make sure that the case you present for why the NHS should take on your product or service is watertight. The organization's procurement procedures are, rightly, very stringent, so there'll free passes if you forget to cover / include / explain something that you should have. To do this, you'll need to know **the [NHS procurement standards](https://www.gov.uk/government/publications/nhs-procurement-standards)** inside out and make sure that your product or service ticks every box.
- <https://www.gov.uk/government/publications/nhs-procurement-standards>



Tenders

- <https://www.ojec.com/>
- <https://ted.europa.eu/TED/main/HomePage.do>
- TED (Tenders Electronic Daily) is the online version of the 'Supplement to the Official Journal' of the EU, dedicated to European public procurement.
- TED publishes 520 thousand procurement notices a year, including 210 thousand calls for tenders which are worth approximately €420 billion.
- TED provides free access to business opportunities from the European Union, the European Economic Area and beyond.
- Every day, from Tuesday to Saturday, a further 2,000 public procurement notices are published on TED.
- You can browse, search and sort procurement notices by country, region, business sector and more.
- Information about every procurement document is published in the 24 official EU languages. All notices from the EU's institutions are published in full in these languages.

Importing CE marked medical devices into the UK

- UK bodies importing medical devices into the UK from outside of the EU become legally responsible under the medical devices directive for those devices.
- Class IIa, IIb or III devices
There are 2 options: 1) Become the Authorized Representative designated by the manufacturer selling under his name; the manufacturer's Notified Body will audit your facility, or 2) If the manufacturer already has an office or an Authorized Representative in the EU, become an 'own brander' selling under your own name and having an agreement with the manufacturer whereby he guarantees that he will supply on demand all the technical documentation associated with the CE marking including changes made since the original approval. You will need to engage a Notified Body to authorize the CE mark under your name; this will probably be the same as the manufacturer's Notified Body. An exception to this if you assemble a procedure pack comprising CE marked products. In this case you only have to make a declaration that you: a) have verified the, mutual compatibility of the devices in accordance with the manufacturers' instructions and have carried out his operations in accordance with these instructions; and b) have packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and c) the whole activity is subjected to appropriate methods of internal control and inspection.
- Class I devices
If the products are Class I devices, it is likely that no third party has been involved in the approval process. Therefore, as the legally responsible person in the UK, you will necessarily need reassurance that the product meets the essential requirements of the directive. You must have access to the technical documentation associated with the CE marking. In all cases you must have procedures in place: 1) to ensure the continuing compliance with the essential requirements of the directive during transport and storage of the products under your control 2) review the experience gained from devices in the post production phase, and to implement corrective actions where necessary. 3) to notify the MHRA of relevant adverse incidents. In all the above cases you must register with the MHRA as either an Authorized Representative or an own branded

Placing a product on the UK market

To place a medicinal product on the market and sell it in the UK, that product must have a valid marketing authorization.

To obtain a marketing authorization, a competent authority must assess the product to ensure that it meets the necessary safety, quality and efficacy criteria. These are set out in the: Community Code.

HMRs.

Regulation (EC) No 726/2004 on the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (EMA Regulation), as amended.

The two main procedures for obtaining a marketing authorization are the:

Centralized procedure, which results in a marketing authorization granted by the European Commission and is valid throughout the EEA.

National procedure, which results in a marketing authorization issued by the MHRA and is valid in the UK only.

Areas of need

- IT infrastructure
- Efficiencies
- Cancer
- Stroke

- **Diabetes**

It is currently estimated that about £10 billion is spent by the UK NHS on diabetes. 10 % of the NHS budget is spent on diabetes.

This works out at around:

- £192 million a week
- £27 million a day
- £1 million an hour
- £19,000 a minute

NHS Focus

- Cost Effective Solutions
- Improving The Quality Of Improving The Quality Of Care And Access To Cancer Treatment
- Tackling Obesity And Preventing Diabetes
- Controlling Costs And Enabling Change
- Delivering Value And Financial Sustainability Through A Step Change In Efficiency
- Developing Leading edge Science And Innovation
- Transforming Care Through Harnessing Information And Technology

Consumers' spending on other wellness and fitness categories



Nutrition

+34%

£500m in 2015
to £670m in 2020



Telehealth

+23%

£260m in 2015
to £320m in 2020



Sports equipment

+21%

£3,900m in 2015
to £4,700m in 2020



Alternative medicine

+18%

£5,700m in 2015
to £6,700m in 2020



Weight loss

+17%

£1,800m in 2015
to £2,100m in 2020



Pilates and Yoga

+17%

£760m in 2015
to £890m in 2020



Personal trainers

+12%

£600m in 2015
to £670m in 2020



Vitamins

+10%

£410m in 2015
to £450m in 2020



Gym membership

+5%

£4,000m in 2015
to £4,200m in 2020