EUROPEAN FACT FILES

HEALTH AND SOCIAL CARE REPORT

2019

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Introduction

With voters heading to the polls in several countries later this year, the European political map may have shifted substantially by the end of 2019. Alongside this the European Parliament elections in May will also act as a key marker to the extent to which populist parties are gaining ground. Meanwhile, Brexit continues to cast a long shadow over the UK's relationship with the European Union.

It is vital that investors stay abreast of these developments and modulate their strategies accordingly, as the shifting political landscape has the potential to deeply impact on health and care policy, regulation, and reimbursement. Despite sharing common features, Europe cannot be viewed as a homogeneous entity, with a one-size-fits-all solution. Instead investors must get to grips with the specific challenges within individual territories.

Health and care systems are tied to their national historical context and cultural preferences. They will shape users' attitudes and expectations, including their willingness to pay to access services or products. These are essential considerations to keep in mind for companies looking to enter the European market or expand a business model from one country to another.

Overall, the European health and care market is an attractive one for investors. The fundamental drivers are common across markets, with people living not just longer, but often with multiple conditions that require long-term care and support. Publicly funded healthcare systems must find ways to fund rising demand, whilst investing in new technology and infrastructure, and improve care quality. This can provide opportunities for investors who are able to offer cost-effective alternatives to traditional delivery models, or offer new solutions that improve efficiency and quality.

To support our clients, Marwood Group produces an annual European Fact File. It provides readers with easy access to essential knowledge about the health and care systems across Europe. This year's edition covers 16 different countries. In light of important regulatory changes coming into force, we have included a section on European Union medical device and pharmaceutical regulation.

Throughout our research, we have found similar policy themes emerging across Europe, as countries tackle system challenges, from demographic change to increased pressure on public services.

1. Social care reform is coming up the policy agenda. It has often been a secondary priority to healthcare, but as countries get to grips with the societal costs of failing to address the ageing population challenge, this is beginning to change. Germany has led the way, with reforms that have expanded access to publicly-funded social care services.

2. Across Europe, policy makers are attempting to lay the foundations for 21st century healthcare systems. Several governments have outlined how data can be leveraged to improve system efficiency and better tailor care to patients' needs. Denmark is a leader in this area, and their 2018 Digital Health Strategy aims to expand digital solutions across the health and care system.

3. Moving service provision outside of traditional inpatient settings is a common objective. This has the advantage of delivering care where it is most convenient for the individual, whilst potentially reducing system spend on more costly locations. In turn, this frees up resources to reinvest in providing support for the most acute, high-cost care needs.

We hope you enjoy reading our European Fact Files Health and Social Care Report 2019, and would be more than happy to discuss further any countries and topics we have covered.

Jyoti Mehan
Director, Business Development
+44 (0)20 3178 2504 / jmehan@marwoodgroup.com

Healthcare System Snapshot

	HEALTHCARE			
	Public Healthcare System: Access Criteria	Public Healthcare System: Sources of Funding	Primary Payers	Healthcare Providers
Belgium	Statutory Health Insurance Universal Access	Employee/Employer Payroll Contributions, National Taxation	Seven Sickness Funds	Majority Public and Non-Profit, Small Private Sector
Denmark	National Health Service Universal Access	National Taxation	Five Regions	Majority Public, Small Private Sector
Finland	National Health Service Universal Access	National and Local Taxation	311 Municipalities	Majority Public, Small Private Sector
France	Statutory Health Insurance Universal Access	Employee/Employer Payroll Contributions, National Taxation	Central Statutory Health Insurance	Public and Private Mix
Germany	Statutory Health Insurance Universal Access	Employee/Employer Payroll Contributions	110 Sickness Funds	Public and Private Mix
Ireland	National Health Service Access Means Tested	National Taxation	Health Service Executive, Individuals	Public and Private Mix
Italy	National Health Service Universal Access	National Taxation	21 Regions, 103 Local Health Authorities	Majority Public, Small Private Sector
Netherlands	Statutory Health Insurance Universal Access	Employee/Employer Payroll Contributions	Sickness Funds	Majority Public and Non-Profit
Norway	National Health Service Universal Access	National and Local Taxation	Four Regional Health Authorities	Majority Public, Small Private Sector
Spain	National Health Service Universal Access	Local Taxation	19 Regional Health Services	Public and Private Mix
Sweden	National Health Service Universal Access	Local Taxation	21 County Councils	Majority Public and Non-Profit
Switzerland	Statutory Health Insurance Universal Access	Statutory Health Insurance Premiums, National and Local Taxation	Sickness Funds, 26 Cantonal Health Authorities	Public and Private Mix
England	National Health Service Universal Access	National Taxation	195 Clinical Commissioning Groups	Majority Public, Small Private Sector
Northern Ireland	National Health Service Universal Access	National Taxation	Health and Social Care Board	Majority Public, Small Private Sector
Scotland	National Health Service Universal Access	National Taxation	14 NHS Boards	Majority Public, Small Private Sector
Wales	National Health Service Universal Access	National Taxation	Seven Local Health Boards	Majority Public, Small Private Sector

Social Care System Snapshot

SOCIAL CARE				
Public Social Care System: Access Criteria	Public Social Care System: Sources of Funding	Primary Payers	Social Care Providers	
Need and Means-Test	National and Local Taxation	Seven Sickness Funds, Regions, Individuals	Public and Private Mix	Belgium
Need-Test	Local Taxation	98 Municipalities, Individuals	Majority Public, Small Private Sector	Denmark
Need and Means-Test	National and Local Taxation	311 Municipalities, Individuals	Majority Public, Small Private Sector	Finland
Need and Means-Test	National and Local Taxation	101 Local Authorities, Statutory Health Insurance, Individuals	Public and Private Mix	France
Need-Test	Employee/Employer Payroll Contributions to Long-Term Care Insurance	110 Long-Term Care Funds, Individuals	Majority Private	Germany
Need and Means-Test	National Taxation	Health Service Executive, Individuals	Public and Private Mix	Ireland
Need and Means-Test	National and Local Taxation	7,000+ Municipalities, 103 Local Health Authorities, Individuals	Majority Public, Small Private Sector	Italy
Need and Means-Test	Employee/Employer Payroll Contributions to Long-Term Care Insurance	380 Municipalities, Sickness Funds, Individuals	Majority Non-Profit	Netherlands
Need and Means-Test	National and Local Taxation	422 Municipalities, Individuals	Majority Public, Small Private Sector	Norway
Need and Means-Test	National and Local Taxation	19 Regions, Individuals	Majority Private	Spain
Need-Test	Local Taxation	290 Municipalities	Public and Private Mix	Sweden
Need and Means-Test	Statutory Health Insurance Premiums, National and Local Taxation	Sickness Funds, 26 Cantons, Municipalities	Public and Private Mix	Switzerland
Need and Means-Test	National and Local Taxation	152 Local Authorities, Individuals	Majority Private	England
Age, Need and Means-Test	National Taxation	Health and Social Care Board, Individuals	Majority Private	Northern Ireland
Age, Need and Means-Test	National Taxation	32 Local Authorities, Individuals	Majority Private	Scotland
Need and Means-Test	National and Local Taxation	22 Local Authorities, Individuals	Majority Private	Wales

European Union Regulation

Medical Devices

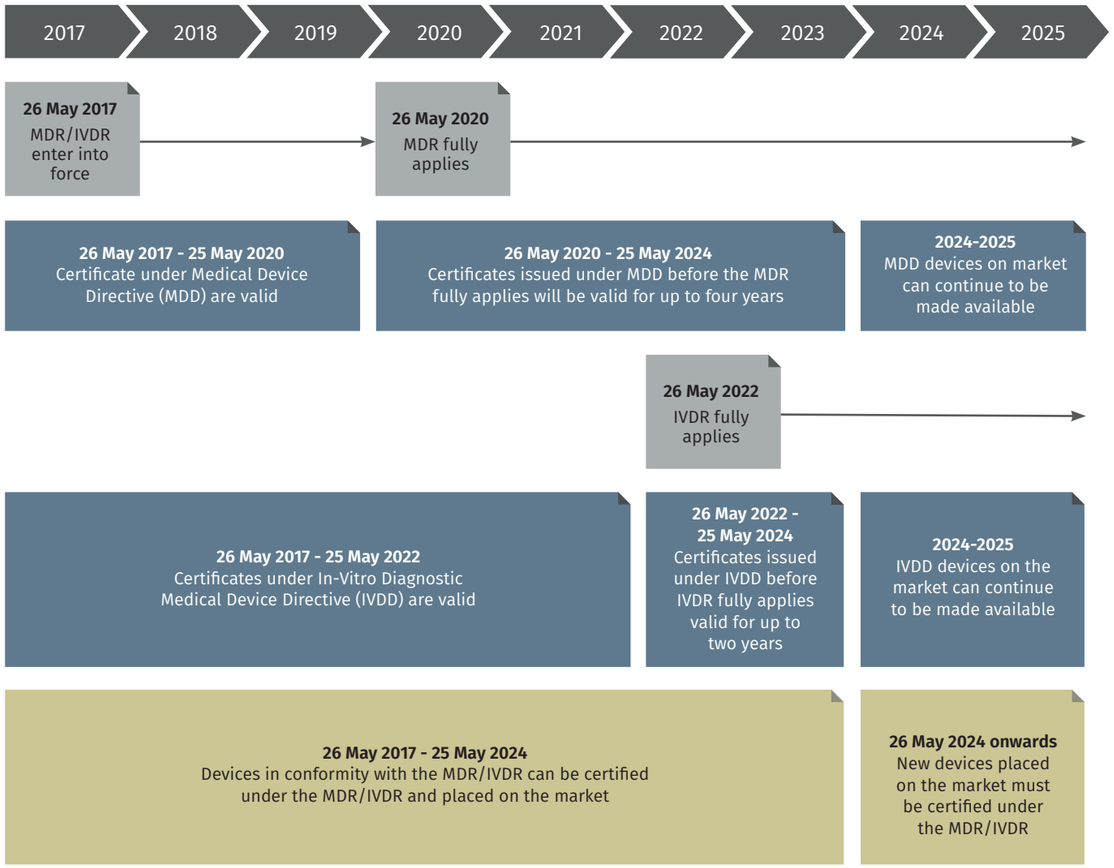
Regulation

Medical technology regulation is primarily set at EU level but is implemented by national regulators (competent authorities) and their Notified Bodies.

To be placed on the market, a medical device must bear a CE mark, granted by one of the competent Notified Bodies. Notified Bodies are private companies that have been entitled by a national competent authority to assess whether manufacturers and their medical devices meet regulatory requirements. When requirements have been satisfied, the Notified Body authorise manufacturers to put a CE mark to their device. There are currently 57 Notified Bodies entitled to deliver CE marks.

The Medical Devices Regulation is due to apply in full by 25 May 2020 and the In-vitro Diagnostic Medical Device Regulation is due to apply in full by 25 May 2022. Devices will need to be re-certified under the new regulations. However, for this to become possible, Notified Bodies need to be re-accredited. Due to the increased requirements on Notified Bodies under the MDR, it is expected that some of them will cease their operations. Their number is due decrease from just under 60 to approximately 35. As a result, MDR re-certification workload will fall on a smaller number of Notified Bodies, which may cause delays in issuing the new certificates.

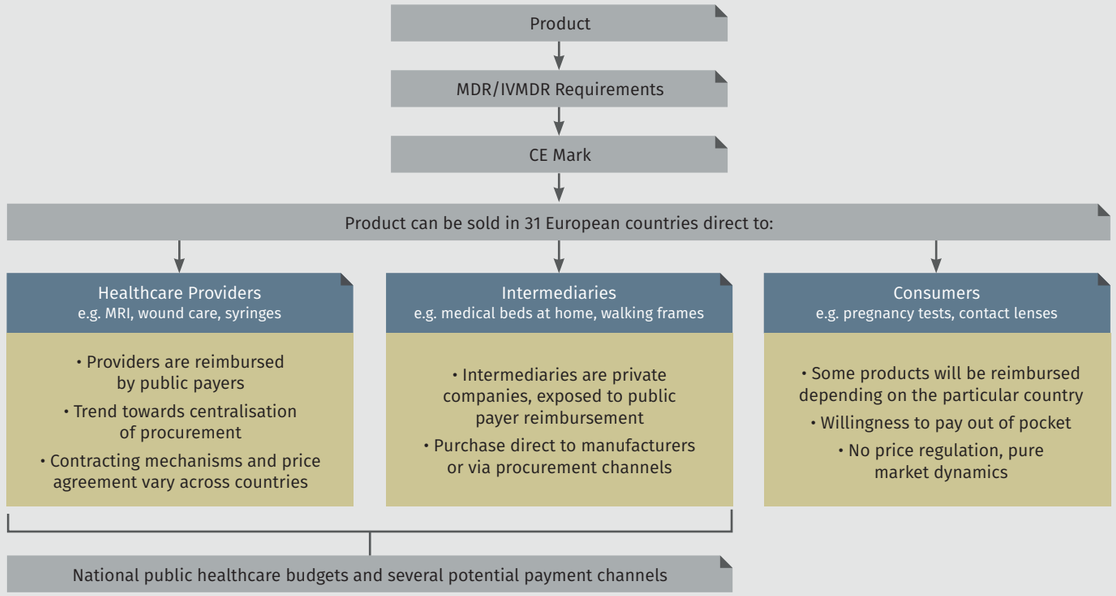
Medical Device Regulation Implementation Timeline



Payment Mechanism

Once a CE mark has been granted, medical devices companies may sell their product in 31 European countries. This includes the 28 EU member states (inclusive of the UK) and the three European Economic Area (EEA) countries; Norway, Iceland and Liechtenstein.

Depending on the type of product and how it will be used, there are three main payers. These are healthcare providers, intermediaries, and consumers. The chart below provides an overview of their key features.



Market

The European medical devices market is estimated to be worth €110bn across the 28 EU countries, Norway and Switzerland. Approximately 27,000 companies employing 650,000 people in Europe are engaged in medical device manufacture. They are located in greater numbers in Germany, the UK, France and Sweden.

Overall, European countries export more medical devices than they import, although at a country level, Italy, the UK, Spain and France import more medical devices than they export. The majority of imports come from other European countries and are facilitated by the EU's single market, an area of free trade. Outside of the single market, Europe's main trade partners are the US, China and Japan. Imports from developing countries are low overall. However, the Confederation of British Industry reports that they grew by 12% on average each year between 2011 and 2015. Germany was the largest importer of medical devices from developing countries, with imports worth €2.3bn, or nearly 15% of total imports.

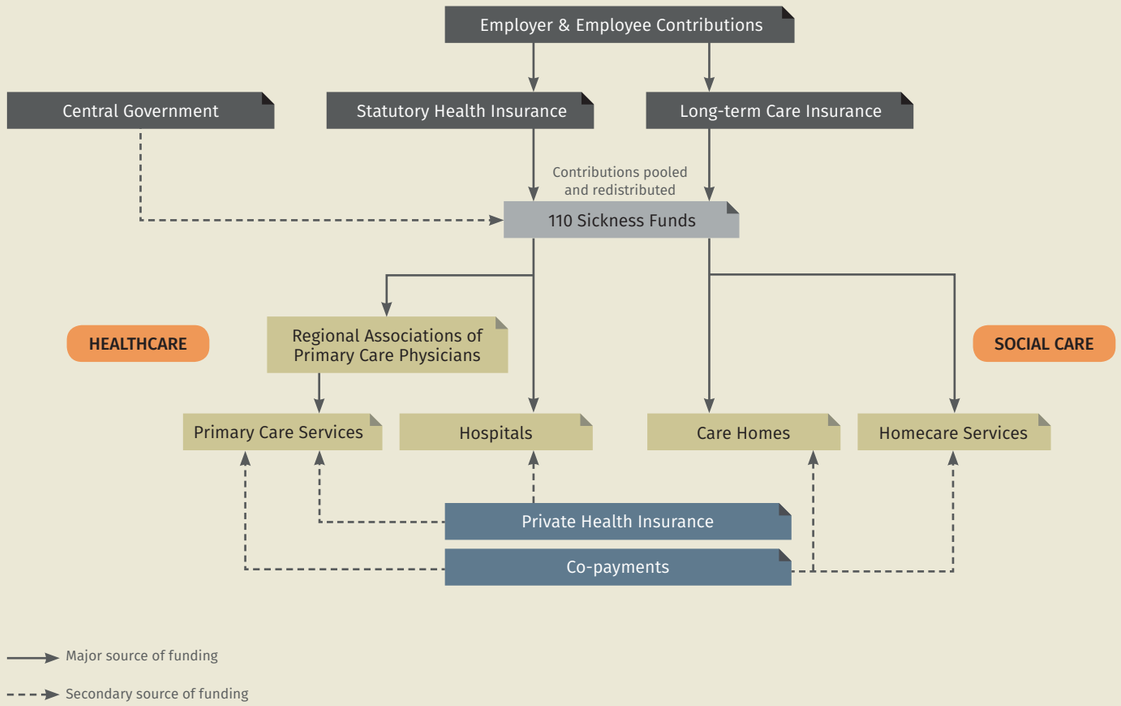
Merger, acquisition, separation, inversion, in-licensing and alliance activity in the sector are driven mostly by the general instruments segment. The ageing population will sustain the demand for medical devices but budgetary pressures on public health systems will likely drive the consolidatory trends and offshoring to cheaper countries for manufacturing.

Germany

Key Messages

- Reform of social care funding and access to publicly-funded services continue to drive changes to the health and social care landscape
- The number of people accessing publicly-funded social care services is increasing, creating additional demand for homecare and care home services, two areas where private operators dominate provision
- The next stage of social care reform will focus on attracting, training and retaining health and social care staff, to address the growing demand for services
- This national policy is implemented at the regional level, with Länder having discretionary legislative and regulatory powers to introduce their own operational requirements
- Regulatory measures are being introduced to support patient choice by improving transparency and quality of information in social care

Funding Flows



Key Facts and Figures

Population

Total

82.8m

Source: Federal Institute for Stats

Life Expectancy

81.8 years

Source: OECD

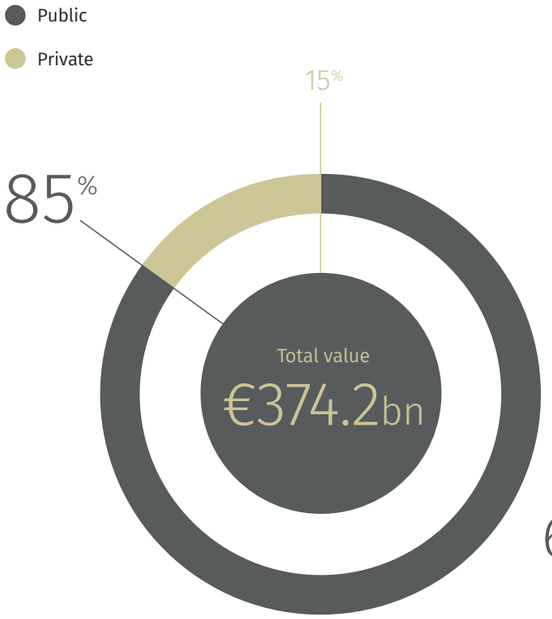
Population Distribution (%)

- 24% are aged between 0 and 24
- 55% are aged between 25 and 64
- 21% are aged over 65

Source: Eurostat

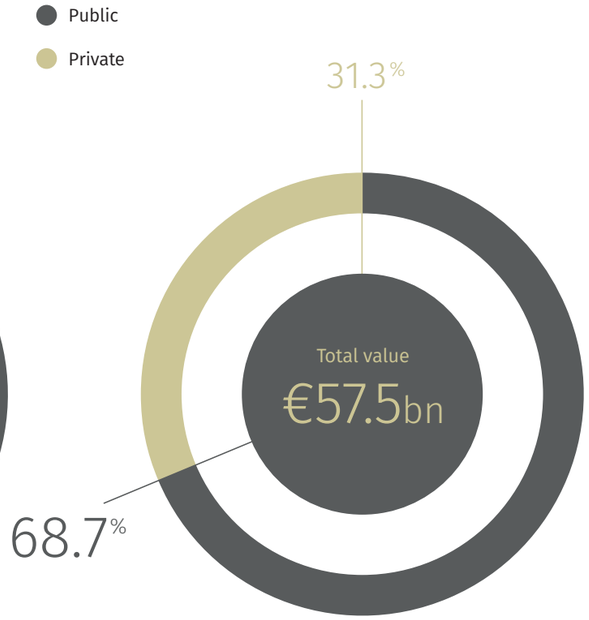
Healthcare Expenditure

Source: OECD



Social Care Expenditure

Source: Federal Office for Statistics, Federal Health Reporting Service, Marwood Analysis



Policy Snapshot: Long-term Care Insurance

Long-term care insurance reform continues to dominate the political and policy agenda

Since 2015, the German government has focused on reforming the long-term care system (i.e. services for older people) to address growing demand for services. Long-term care is expected to remain a priority over the next few years, with focus shifting from legislative changes to implementation. This will be driven by the Länder (regions).

A total of five acts addressing various aspects of long-term care were passed between 2015 and 2017 and constitute the biggest reform of the German long-term care insurance since its inception in 1995. There are three key elements to the reform:

- Funding: payroll contributions increased from 2.05% to 2.35% in 2015, and to 2.55% in 2017 (those without children pay 2.8%)
- Access to services: eligibility for LTCI funding was widened, with a new assessment system introduced from January 2017. The objective was to expand assessment criteria to take into account the needs of those affected by dementia. As a result, the number of recipients of LTCI funding increased from 2.7m to 3.3m between December 2016 and December 2017
- Workforce: as demand for long-term care services is set to grow, the current phase of the reform is focused on attracting, training and retaining the appropriate workforce. This is likely to include salary increases and a common curriculum for both health and social care nurses. From 2019, minimum staffing levels apply for certain hospital services, such as geriatrics. This could progressively be extended to other services for older people, including care homes.

Healthcare

Funding

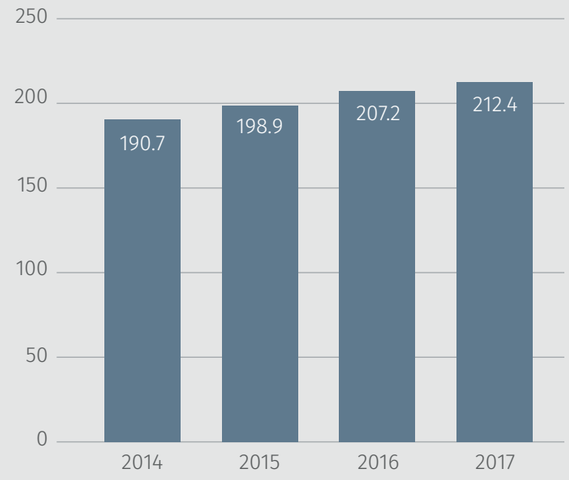
Healthcare funding is primarily public and comes from mandatory payroll contributions to the Statutory Health Insurance (SHI).

SHI expenditure grew at an average annual rate of 3.6% between 2014 and 2017, reaching €212.4bn in 2017. However, the reliance on employee and employer payroll contributions as sources of funding means that there is long-term pressure due to a shrinking working-age population relative to a growing older population. By 2030, population projections predict a ratio of two working age adults per older person. This will be a significant decrease from approximately three to one currently.

Sickness funds are not allowed to register deficits. Anticipating future funding pressure, they have built financial reserves, estimated to be worth €15.9bn across all funds at the end of 2016.

SHI Expenditure (€, bn)

Source: Federal Office for Statistics



Contact us

For more information on any of the content in this publication or to learn more about Marwood Group's advisory capabilities, we encourage you to please contact us.

Jyoti Mehan
Director, Business Development
Office: +44 (0)20 3178 2504
jmehan@marwoodgroup.com