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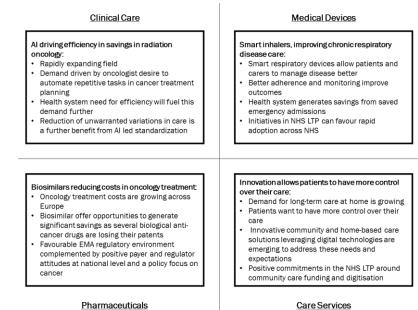
Healthcare in Europe: Sector trends to watch in 2019

FOLLOW US ON SOCIAL MEDIA Marwood Group LinkedIn As investors and operators know first-hand, healthcare is not a sector that stands still. The operating environment constantly faces multiple headwinds that drive change. These can be innovations within a sub-sector that provide more efficient or effective offer to payors, or it might be top-down shifts in government policy that are reactions to changing demographic demands and rising expectations from individuals about what they expect from a publicly funded service.

There are many ways to navigate a path through to successful investment in healthcare sub-sectors. However, one key area is to ensure that investment is capitalizing on emerging trends and be well positioned to take advantage of new demand opportunities in the market.

Some of the fundamentals may remain constant - demand for quality healthcare at affordable prices and innovation through technological advances in pharmaceuticals, medical devices and service models are not new dynamics. However, as the operating environment changes it is important to remain aware of where these dynamics are impacting.

In this article, we have selected four areas that highlight these dynamics and have the potential to disrupt the market, providing opportunities for investors and operators.



1. Clinical Care

Artificial Intelligence (AI) in radiation oncology is likely to introduce significant efficiencies in cancer treatment planning and delivery

Artificial Intelligence (along with robotics, nanotechnology, quantum computing, biotechnology and IoT) has been described as the fourth industrial revolution. Al is making inroads across the healthcare spectrum and is continuously improving its offer. Radiation oncology could benefit significantly from Al as it will likely drive efficiencies in the planning and delivery of radiation treatment to patients.

Over a million patients in the US and over 130,000 patients in England undergo radiation therapy each year. The potential efficiency and outcome benefits that can accrue to this population could be very significant.

Radiation therapy for cancer involves meticulous planning of where and how the radiation dose is to be delivered to target the maximum amount of cancer tissue whilst preserving neighbouring normal tissue. Traditionally, this would require the input of a Multi-Disciplinary Team (MDT) over several days, but Al can cut this time down to a few hours.

By using AI software enabling target and normal tissue segmentation, preliminary planning can be completed in a relatively short duration (as short as 20 minutes in some cases) and then only requires fine tuning and QA by the MDT, which can be accomplished within a few hours. Other areas where AI can support radiation oncology is in providing dose optimization and offering clinical decision support.

At present, examples of key players in this field include Google's DeepMind, Mirada Medical's DLCExpert, Siris Medical's QuickMatch, and Oncora Medical's Precision Radiation Oncology Platform. Some academic institutions like University of Toronto have also developed their own Al solutions.

As radiation oncology data gets richer through international academic and commercial data cooperation efforts (e.g. EuroCAT, OncoSpace and Flatiron Health) Al should only improve, and experts expect it to replace several human functions in the field.

Cancer is one of the largest spend areas for developed health systems and the need to optimize the cost of delivery of care will likely drive adoption of these technologies on the ground. The value offer to under pressure healthcare systems is clear; adoption should free up specialist staff to enable more time spent on other aspects of clinical care, whilst more optimal and efficient care planning should allow for a higher throughput of patients in the treating unit.

Company Profile Example: Mirada Medical

Mirada Medical developed as a spin-off from Oxford University as an imaging software company. They identified a demand amongst radiation oncologists to automate certain routine and timeconsuming aspects of cancer treatment planning. The company's solution – DLCExpert - came from research projects focused on these solutions.

With its AI based approach to organ contouring for radiation dose planning DLCExpert cuts down significantly on the planning time, reduces unwarranted variations in care planning and increases throughput in the system. The NHS target wait between decision to treat a cancer and delivery of treatment is 31 days currently, but there is a movement to bring it down to 14 days. This would put immense pressure on radiation oncology units and likely positively impact the demand for efficiency enhancing solutions.

Receiving a CE Mark in February 2018, and granted FDA clearance in July 2018, DLCExpert is already in use in cancer treatment in Europe.

2. Medical Devices

Smart inhalers that monitor inhaler use and transmit usage data to healthcare professionals could revolutionize asthma and Chronic Obstructive Pulmonary Disease (COPD) management

Asthma and COPD are major causes of death and disability globally and their incidence is rising. The World Health Organisation estimates that approximately 334m people globally suffer from asthma and about 65m suffer from COPD. COPD kills 3m people globally each year making it the third leading cause of death worldwide.

Inhaler therapy is the primary treatment option for these conditions. However, adherence to prescribed preventive inhaler use has been identified as an issue especially in the very young and elderly. Also, patients suffer from an inability to effectively track their inhaler use, and risk being caught using an empty inhale as a result of being unable to gauge the quantity of medication in the inhaler.

Are smart solutions the answer? Approximately 210m people with chronic respiratory disease have access to a smartphone or device, and the smart respiratory devices market has been predicted to reach \$557m by 2023. Increasing incidence of chronic respiratory disease, increasing penetration of smart devices and patients' demand for more control over their care will likely drive growth in this market. Smart inhalers are expected to be a significant component of this segment's growth

Adherium and Propeller Health have been examples of leaders in this space, but new entrants are introducing new products to the market. Recently, the Israeli pharmaceutical company Teva obtained FDA approval for its ProAir Digihaler and is expected to launch across the USA by 2020. Other examples of companies to watch in this space are Inspiro Health and Cohero Health.

Smart inhalers: how they benefit patients and clinicians

- 1. Tracks usage of preventive and curative inhalers
- 2. Sends usage data via bluetooth into a secure platform database
- 3. Sends medication reminders and missed dose alerts
- 4. Allows permitted healthcare professionals to monitor usage and intervene early to prevent catastrophic episodes as needed
- 5. Enables patients to track their medication use and inform them about the quantity of medication left in the inhaler

European healthcare systems often share similar healthcare challenges among their populations, and in several geographies there is an increasing focus in many countries on how connected care technologies could form part of a solution of more empowered and aware patients managing their own health.

The recently released NHS Long Term Plan (LTP) is a strong example of this. There is a heavy emphasis on the use of connected care technologies and personal health budgets. The LTP aims to enable 2.5 million people by 2023-24 to access personalized care packages and use Personal Health Budgets (PHBs) to live better with their long-term illnesses. Since both asthma and COPD are long-term illnesses, patients could qualify for funding from PHBs for these smart devices. Better adherence and monitoring have been shown to improve outcomes and decrease emergent episodes thereby creating value for the healthcare system.

This creates two potential revenue streams within a public pay market; (1) traditional prescription direct from a healthcare professional, and (2) individuals that potentially use PHB budgets to purchase services and equipment that support them to manage their own care.

Company Profile Example: Propeller Health

Founded in 2007, Propeller Health is one of the pioneers in the smart inhaler industry. They make sensors that fit into patients' existing inhalers and allow usage and dose monitoring. This helps patients better manage their conditions, identify triggers for attacks and work with their healthcare professionals to optimize care efficiently.

The product has been studied in over 15 clinical studies covering more than 2,500 patients, and is currently in use in 40 commercial programmes across the US. Studies have demonstrated impressive results – average 79% reduction in rescue inhaler use with continued use of the technology for 1 year (p<0.0001) has been witnessed across all patients on Propeller's device.

In December 2018 the respiratory medicine specialty company ResMed announced the acquisition of Propeller Health for \$225m.

3. Pharmaceuticals

Biosimilars could provide attractive solutions for public payors looking to manage escalating oncology treatment costs

With more and more biologic drugs approaching patent expiry in Europe, payors are keen to leverage the savings potential from their cheaper biosimilar versions. Medicines for Europe, the trade organisation representing biosimilar manufacturers, estimates that biosimilar usage will have saved governments from \pounds 11.7bn to \pounds 33.4bn between 2007 and 2020. The growth potential in the market is such that between 2017 and 2023 the European biosimilar market is projected to grow from \pounds 2.01bn to \$9.17bn (a CAGR of 29%).

Oncology is a key market for biologics, with IQVIA estimating a total European expenditure on oncology of \in 24.2bn in 2016, an increase of \in 2.9bn from the previous year. The savings potential from the use of biosimilar replacements in oncology treatment are attractive for healthcare systems looking to reduce expenditure on pharmaceuticals. It appears that manufacturers are responding to this demand, as in January 2019, 8 out of 19 biosimilar marketing authorisation applications with the European Medicines Agency (EMA) were for anti-cancer drugs.

Manufacturers could benefit from a favourable regulatory context., with the EMA being at the forefront of biosimilar regulation. Over the past 10 years, the agency has continuously clarified its regulatory framework used to establish the similarity of biosimilar to the biologic reference product. The average assessment time for biosimilar application approval has reduced from 200.7 days in 2015 to 175.5 days in 2017.

The EMA's positive regulatory approach to biosimilar marketing authorisation is complemented by favourable payers, regulators and policy makers' attitude at the national level. All EU countries have agreed in principle that no additional clinical studies on switching are needed once a biosimilar has received EMA approval, with many territories producing specific switching guidance. For example, in 2017.

NHS England introduced a biosimilar commissioning framework to support NHS commissioners, prescribers and patients to make informed decisions on the use of biosimilar. Read in parallel to the NHS Long-Term Plan, which sets ambitious objectives for cancer survival, it suggests opportunities for biosimilar uptake in this area. Elsewhere in Europe, the Italian Medicines Agency released a position

paper in May 2018, encouraging prescribers to use their clinical judgment in switching to biosimilar for patients treated with a reference biologic.

The favourable environment creates opportunities to stimulate the entire biosimilar value chain, from well-known large players like Pfizer or Mylan to niche contracting manufacturing organisations who benefit from the outsourcing of highly specialist development work.

Drug Product Example: Rituximab biosimilars gaining market share

Rituximab is a chimeric monoclonal antibody used in the treatment of certain blood cancers, such as chronic lymphocytic leukemia. The originator Rituxan (Roche), with global sales worth €6.4 billion, had its European patent expire in 2013. The first biosimilar version got EMA regulatory approval in 2017. There are now six biosimilar versions on the European market, sold by large pharmaceutical companies such as Sandoz and South Korea Celltrion.

As of October 2018, the uptake of rituximab biosimilars had made significant progress. In the UK and the Netherlands biosimilars made up over 90% of rituximab prescriptions. In Italy, the rate was close to 75% of all prescriptions, while in France and Germany it was just over 60%.

In Q2 2018, Sandoz reported that its European sales were up 12.9% compared to Q2 2017. The company identified rituximab sales as a key growth driver.

4. Care Services

A new generation of innovative community and homecare services will likely support the provision of person-centred care outside of hospital

The growing demand for long-term care is challenging traditional models of health and care organisation across Europe. One of the major trends developing in recent years is a real focus on shifting care delivery out of inpatient settings and into people's homes.

This community care model encompasses a wide range of health and social care services and seeks to address the needs and expectations of individuals across a wide spectrum of ongoing care needs. Although it may be most commonly seen as supporting frail older people living with chronic conditions, it also includes any adults with complex care needs, and people who may require end-of-life support.

Demographic factors will sustain demand from these groups. The number of people over the age of 80 living in the European Union is projected to more than double by 2080, rising from 27.3m in 2016 to 66.1m in 2080. There are multiple studies that highlight how the patients have rising expectations over the amount of choice they can exercise over the type of care they receive and how it is delivered.

In response, we are seeing the emergence of innovative community care providers. Business models will be flexed within national geographies to reflect the health and care systems they operate within, but they share a common theme in offering more efficient service delivery, whilst giving patients and their families more choice over their care arrangements.

Digital technology is often at the heart of this offer. Companies, such as Tunstall, have been pioneering telecare solutions enabling people to live independently in the community – and their penetration into multiple European countries appears to demonstrate that this service model can adapt to fit the needs of specific healthcare markets. New entrants into this space are also leveraging the latest innovations to differentiate their products, for instance UK-based Cera Care is a community care service provider, which has developed an Uber-style online platform to match patients with its carers.

Whilst community care services have traditionally not enjoyed significant policy and political attention, their profile has been rising in recent years. In England, the NHS Long-Term Plan committed £4.5bn additional real-term funding for primary and community care services between 2019/20 and 2023/24. This will be on-top of the current £10bn per year spent on community care services. If the objective to increase the number of personal health budgets from 40,000 to 200,000 is reached, it will increasingly put the individual at the centre of decision making.

England is not alone in these trends. The continuing reform of Long-Term Care Insurance (LTCI) in Germany has strengthened the principle of 'home before inpatient care'. The reform widened eligibility access to LTCI funded community and home-based care services, with the number of recipients increased by 28% between 2016 and 2017 (1.97m to 2.52m).

This creates positive headwinds for operators and investors as it widens the potential pool of people receiving services at home, with larger numbers having direct control over the services they access. The increased reliance on technological innovation also provides opportunities for business models to be replicated across national boundaries.

Company Profile Example: Cera Care

Cera Care is a provider of community care services for older people and individuals requiring ongoing personal care support. The company has developed an Uber-style online platform allowing users to request services when they need them, giving them control over their care schedule. A matching algorithm and automated scheduling systems enables Cera Care's carers to respond to enquiries within the hour.

Innovative use of technology has allowed streamlined operations, minimal reliance on administrative staff, and a focus on developing frontline services.

Founded in 2016, Cera Care has grown rapidly, and acquired both Radcliffe Home Help Services and Yorkshire's Advanced Community Healthcare in 2018.

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