MARWOOD GROUP

2022 European Healthcare Policy Primer

- Healthcare conversations continue to be dominated by pandemic crisis management. This may remain the case for the next few months as the Omicron wave peaks across Europe. However, there are wider challenges to contend with and across 2022 macro events are likely to shape issues that investors across the healthcare and life sciences spectrum need to consider
- In England, the government needs to push on with its wider public reform agenda. The NHS Health and Care Bill may shape healthcare reform, but there are also important policy and regulatory reviews expected within the children services sector that are likely to impact across foster care, care homes and special educational needs provision
- In France, all eyes will be on the French presidential election. President Macron may not have yet formally declared himself as a candidate, but he currently leads the opinion polls. The outcome may depend on whether the election becomes a snap-judgement on his handling of the pandemic, and whether the two-stage electoral system leads to a run-off with an extreme or moderate alternative
- In Germany, a new era dawns as the country finds itself without the presence of Angela Merkel as Chancellor, or the CDU in government. The focus will be on whether the untested Traffic Light coalition can hold itself together and push forward with delivering on its coalition promises
- At the European Level, regulatory change continues that will impact across all Member States. Most prominent is the In-Vitro Diagnostic Regulation coming into effect on 26 May – following the Medical Device Regulation, which came into effect last year. However, Clinical Trial Regulations and a broader review of general pharmaceutical regulations will also contribute to a changing operating environment

As we kick-off 2022 at the Marwood Group we are aware that ongoing political, regulatory, and legislative changes across Europe will continue to have a far-reaching impact on the viability of healthcare and life sciences investments across sectors.

To support client decision making, we will continue to publish our Thought Leadership pieces that will provide insight into the key impacts affecting the healthcare and life sciences industries.

Our 2022 Political Primer gives a high-level overview of areas of current focus for the Marwood Group across key European markets. We will continue to follow these events as we progress through 2022 and will explore these changes in-depth and provide additional insight on specific pieces of regulatory and legislative change.

These sit alongside our regular market-specific analyses – and we will begin the year by circulating a 2-parter on the CDMO landscape for medical devices and pharmaceuticals, a segment where investor appetite appears to continue to grow.

England: Can the Government push on with its wider health and care system reforms?

The focus on pandemic recovery and the pressures on the NHS has unsurprisingly been the primary focus of the national media over the last year. It ties into a much broader narrative around economic recovery and personal restriction – made even more newsworthy by the continuing revelations surrounding lockdown breaches within No. 10.

The result of this focus on the personal failings of the government has been that wider public service reforms, across health and care services, have faced relatively little public scrutiny. This could change in the first six months of 2022, with a raft of legislation, policy and regulatory reviews in areas that are traditionally of high interest to voters, such as NHS and educational reforms.

Ever the populist – and with one eye on his falling approval ratings and another on the pathway through to the next election – Boris Johnson may be required to make some difficult choices in the months ahead. Backbenchers will be pushing for tax cuts coming into an election, and will be cautious of spiralling public funding commitments, whilst the pandemic funding has cut the headroom for investment. Meanwhile, the public – particularly those who turned to the Conservatives in the northern constituencies – will not look too kindly on a failure to invest in crumbling public services.

It is important for investors – when considering assets that rely on public and private pay segments – to stay on top of these complex issues and work through what the potential scenarios may mean for future revenue targets.

Sector	Things to watch out for
Healthcare	• Pandemic management will be the focus of the NHS in the first months of the year – with Sajid Javid confirming a new deal that will have the private sector on standby in the event that hospitals cannot cope. However, there will be hope that receding Omicron threat marks a new stage and the system can focus on elective recovery • The major focus will become the **NHS Health and Care Bill.** The government's majority has meant a relatively serene passage through the House of Commons, whilst the technical nature of most of the proposals has meant that the media have found it difficult to gain a clear narrative. • The main focus has been on increased powers for the Secretary of State but for private providers and investors the key changes lie in the proposals around a shift to system working and the development of provider collaboratives • One of the potential points of contention will be whether workforce planning is built into the legislation. This is an area where there is pressure across the system to see change – but where the Treasury who ultimately hold the purse strings has been understandably reluctant to support such an open-ended commitment
Social Care	• The major announcements for social care came with the **Health and Social Care Levy** announced in Q4 last year • Leaving aside whether the funding levels are sufficient, the proposals radically shift the levels at which individuals may qualify for public pay support. However, these changes will not come into effect until October 2023 – giving providers another 18 months to work through what this will mean for the revenue base • Of more immediate impact is the compulsory vaccination on social care staff. Already in effect for those that cross the threshold into care homes, it is set to be rolled-out to home care workers from April 2022 • Mitigating the likely impact on jobs, the Government has announced that **care staff be added to the Shortage Occupation List** for at least 12 months. This comes with a minimum salary threshold of £20,480
Children Services	• Q1 2022 is shaping up to be a critical moment for children services, with a series of policy and regulatory documents are expected to be published. It is important that investors stay on top of these developments, as the outcomes will be complex and multi-dimensional, with the impacts likely to be heavily provider specific • The **CMA's Children Social Care Study** is due for publication in February 2022. It is looking specifically at foster care and children's homes (but not SEN provision) and given the potential scope of levers at the CMAs disposal, the sector is rightly following it closely. However, the interim report did suggest that more radical suggestions around fee or profit capping were set to be discounted, with softer regulatory levers at the forefront of their thinking • The **Independent Review of Children Social Care** is expected to take on board the CMA proposals and will report their findings in Q1 2022. This seems more focused on the broader levers impacting on the system. It is likely to bang the drum for more funding, which would be likely to benefit all providers by relieving pressure on local authorities • The much-delayed **SEND Review** seems set to be finally published by Easter. The focus is expected to be on lower complexity individuals and ensuring that the EHC process works effectively. However, there will be knock-on impacts on high-complexity providers. This may tie in with a rumoured **Schools White Paper**, potentially also published in Q1

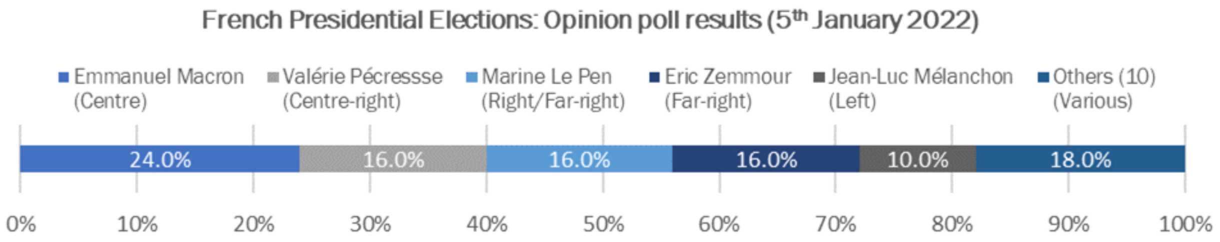
France: What 5 years under Macron has meant for health and social care in France, and what could change in April 2022?

April 2022 will see French voters return to the polls and provide their verdict on President Macron's first term in office. With the latter-half of his term dominated by pandemic crisis management, it feels a long-time since he swept aside historic voter alignments by creating his own centrist, pro-European political movement, La République En Marche.

Over his presidency, Macron has introduced important reforms in healthcare, of which some are already beginning to bear fruits particularly around widening access to care. For example, the '100% Health' reform now allows some optical, auditive and dental care to be 100% reimbursed, and new lump-sum hospital pricing packages have been agreed for the treatment of two chronic diseases (diabetes and renal failure) as first step towards moving away from the activity-based pricing system.

Policy change has been supported by funding injections. The future of healthcare discussion (Ségur de la Santé) resulted in a €19bn injection over 10 years to modernise the country's health infrastructure, as well as a separate €8.25bn per year added to the healthcare budget to raise salaries and make HCP jobs more attractive. As a result of the Ségur, health insurance expenditure targets (ONDAM) will increase by 3.8%, against a quinquennial norm of 2.3%.

More recently, in response to the country's failure to develop a Covid-19 vaccine, Macron released the Health Innovation Strategy 2030 – supported by a further €7bn investment towards reinforcing France's biomedical research capacities, investing in innovative biotechnologies, and simplifying and accelerating clinical trials processes in order to reduce international reliance. Underpinning this investment is an ambition to make France a European leader in the life sciences sector.



Source: www.harris-interactive.fr

Despite not yet being an official candidate, Macron is in the lead to be re-elected this year. He currently polls at 24%, with a fragmented field behind him. The left-wing is in disarray with multiple candidates and unable to unite behind a single figurehead. Whilst the two-stage election system can throw up surprises, at present Macron is likely to be in a run-off with a candidate from the right.

Macron's preferred final round opponent would be the more extreme candidates in the veteran Marine Le Pen, or the emerging Trump-style controversialist, Eric Zemmour. Both would likely cause the left to pull behind a more centrist candidate. A tougher final round opponent may be Valérie Pécresse, who sits far closer to the centre-ground and offer a more credible alternative.

It remains to be seen whether Macron's bullish stance on increasing restrictive conditions for the unvaccinated will play in his favour – with 73% vaccinated may be a calculated political risk. However, populist candidates are already using it as a divisive issue to drive a wedge in the voter base – and it seems likely that 'Covid passes' may become one of the election's defining themes.

The continuing pandemic means that radical health and social care proposals are unlikely during the election campaign. Macron would be expected to broadly continue his current agenda, whilst Pécresse has proposed providing greater regional ring-fenced funding and reinforcing public/private sector collaboration. This may help to support private sector investment. She has also proposed developing domiciliary care through the country, which may help to reignite social care reforms set-out in the Libault Report and that inevitability lost traction in the midst of the pandemic.

Germany: What next for German healthcare policy in a post-Merkel government?

January 2022 marks the beginning of a new era in German politics. It is the post-Merkel era – the veteran German chancellor had been in post since 2005, a period that covered four US Presidents, and five UK prime ministers. It encompassed the Iraq War, the 2008 economic crash, Brexit and a global pandemic.

A key question for the country is how the political system adapts following the departure of a genuine political heavyweight? The situation is made tougher by election results that suggested the country was in the mood for a change. Whilst coalition governments are relatively common in Germany, the 2021 results led to a situation where the most feasible option was a three-way alliance between the SPD, the Green Party and the Free Democrats. This broader alliance has never been previously tested and will need to overcome divergences of opinion, as viewpoints span the political spectrum.

For healthcare providers and investors there will be considerable relief that the health portfolio has been placed in the hands of the experienced moderate politician, Karl Lauterbach.

Lauterbach switched from the CDU to the SPD early in his career and has developed extensive experience of health policy – having spent 2005-2013 in roles serving on the Health Committee and as Health Policy Spokesman for the SPD.

Inevitably, pandemic management has been top of his to-do list. His appearances in the German media and on Twitter have suggested a critic of a quick relaxation, and so it is no surprise the pandemic protective shield has been extended to the end of March 2022.

The challenge for the Minister will be working with his Alliance colleagues to pass necessary legislation that may cut across political lines. Whilst Germany rarely introduces radical legislation swiftly, the new political order may seek to avoid policies that would create too much friction within the governing parties.

The Alliance's plans were published in November 2021, and we set out some of the broader themes that healthcare and life sciences investors may want to consider below.

- *Shifting away from in-patient services to more community orientated care options*

Using reimbursement reforms and changes to the DRG tariff it appears that the new government is keen to reduce its reliance on hospital-based care

- *Continue with the increased digitalisation of the healthcare system*

A focus on improving technology to support both back-end and front-end healthcare delivery. The continued roll-out of Electronic Health Records seems likely, whilst also ensuring that users are benefitting from virtual healthcare services – with specific reference to video and tele-consultation services, and increased telemonitoring

- *Improving care for the most vulnerable*

A commitment to produce an action plan by the end of 2022 to support the care for severely disabled children and increasing the number of treatment centres for adults with disabilities in all federal states. There is also an intention to reduce waiting times for mental health services for children and young people, and in areas where current support systems are weak

- *Managing the pharmaceutical budget whilst ensuring the supply of drugs*

Perhaps where it is most difficult to thread the needle is in pharmaceutical policy. There is a firm commitment to ensure the supply of innovative drugs, but there are also strong hints that pharmaceutical expenditure needs to be controlled. This includes a likely extension of the AMNOG price freeze, providing health insurance funds with options to limit drug prices, and reducing the free pricing window by introducing a negotiated reimbursement price in Month 7, rather than in Month 13

European Union: What can be expected from regulatory changes across medical devices and pharmaceuticals in the year ahead?

Pharmaceutical and medical devices manufacturers will be familiar with the dual focus in Europe, which results from having to consider policy and reimbursement questions through the prism of national governments, whilst focusing broader regulatory considerations on changes occurring at the level of the European Union.

For new life sciences investors this can seem like a challenging and opaque landscape to navigate, and the nuances can be complex. However, it is worth remembering that this reflects a considerable shift towards regulatory harmonisation and has removed the need to gain separate product safety certification in each of the member states – considerably lowering the regulatory burden.

The major regulatory change in the year ahead will be In-vitro Diagnostic Device Regulation (IVDR) coming into effect on 26 May 2022. This follows the Medical Device Regulation (MDR) coming into effect in 2021 and marks a major shift in regulatory compliance for medical devices. Existing dossiers may need to be reconsidered – with consideration as to whether new clinical evidence needs to be generated – whilst new products should not be aligned with existing risk classifications.

However, other regulatory changes continue that should not be forgotten. The Clinical Trials Regulation finally becomes applicable at the end of January 2022, replacing the existing Clinical Trials Directive, whilst a broader review of EU general pharmaceutical regulation is likely to slowly progress in the background.

Life sciences investors should seek to keep track of these developments ahead of asset transactions that have a European presence or may seek to expand into Europe in the future. The implications may be felt through existing product portfolios, but also should be considered in the context of looking ahead at potential pipeline developments to fully understand the potential impacts on future revenue assumptions.

Regulatory Area	Marwood Group Selected Commentary On Regulatory Changes
Medical Devices	• All new products coming onto the market will need to adhere to the new risk classification and the conditions of the MDR/IVDR. This is likely to significantly increase the number of IVDs that require formal oversight pre-approval • Existing products on the market cannot be 'grandfathered' into the new regulations. They will need to re-certify under the new system, and may have to re-assess their existing technical and clinical documentation to ensure compliance • Existing Medical Device Directive certificates will remain valid until May 2024. This is a transition period, which gives companies time to bring existing product documentation in line with new regulatory requirements • Quality and safety standards are increasing. This is likely to increase the cost of compliance, but gives greater assurance to investors about the risks associated with a company's portfolio • Guidelines to provide greater clarity on processes, roles and responsibilities on different actors within the process should help reduce regulatory complexity
Clinical Trials	• The Clinical Trials Regulation becomes applicable from 31 January 2022. At this point it will repeal the existing Clinical Trials Directive, and national legislation that underpins the Directive • Through the implementation of an EU-wider Clinical Trials Information System (CTIS), it aims to harmonise clinical trials conducted across Member States; improving transparency and patient safety • Changes are expected to improve the efficiency around clinical trial operation in Europe, but ongoing concerns remain over how confidentially sensitive information will be handled to avoid it falling into the public domain
Pharmaceuticals	• As part of the EU's general pharmaceutical strategy (2020), there was a commitment to review existing regulations for medicinal products to ensure they remain fit for purpose • One key aspect is reviewing the opportunity to mainstream orphan drugs into broader pharmaceutical regulations and to review the existing incentives. A focus area has been how to ensure drugs that meet clinically unmet need are developed but also remain affordable • The EU has set ambitious timelines for this work but past experience would suggest active regulatory change would take far longer to be implemented. It can be expected that any proposals will attract significant stakeholder interest – from national government, industry and patient groups – and slow down the planned pace of change

Contact Us

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

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