Navigating Brexit

Considerations for life sciences companies

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Do you have a plan to navigate the unknowns?

Life sciences companies, either headquartered or with substantial operations in the UK, must now begin to plan for a future outside the European Union (EU) following the UK referendum on 24 June in which the UK people voted to leave the EU. The UK Government must now invoke Article 50 of the Lisbon treaty to trigger the leaving process. Precisely when they will do this is uncertain — probably the end of 2016 or early 2017. At that point, the UK Government has up to two years to leave the EU, during which time it can negotiate a withdrawal agreement.

The initial aftermath of the Brexit referendum was a political earthquake in the UK and widespread concern about far-reaching economic aftershocks. Much is uncertain across the political, regulatory, economic and financial landscapes until the terms of the exit are negotiated and agreed with the EU (which includes agreement from all the other 27 EU participating countries). Companies therefore need a plan to navigate the unknowns. For example, how will the drug approval processes now operate? How will supply chains be affected by the new trade agreements? What will be the effects of parallel trade in both the short and longer term? What are the tax, regulatory and legal considerations that need to be addressed? How can M&A and capital deployment be optimized?

There are about 70,000 people working in the life sciences industry in the UK. Approximately 7% of these workers are non-UK EU nationals. What will Brexit eventually mean for them? The question of whether free movement of labor should be possible between the UK and other European countries was an issue at the heart of the referendum debate. Until the exact terms of the exit are known, the employment rights and options for that 7% remain uncertain.

Despite the many unknowns, for now, companies can best position themselves for the challenges and opportunities that will emerge by carefully considering potential scenarios and the relevant issues.

Will the UK choose the hard or soft option?

As Theresa May takes over from David Cameron as Britain's Prime Minister and begins to ready her Brexit team, much of the initial post-Brexit political turmoil has subsided. Yet before Prime Minister May invokes Article 50, her team must decide a basis upon which to negotiate the exit. Will it be a soft, hard or somewhere-in-between approach?

Under a soft exit, the UK would adopt a position similar to Norway's, departing from the EU but not the European Economic Area (EEA). Retention of membership in the EEA would allow the UK to share some of the same benefits as EU Member States. Financial markets are currently operating on the assumption that this is very likely the option the UK will pursue.

A hard exit, on the other hand, would put the UK on the same footing as Switzerland. With membership in neither the EU nor the EEA, Switzerland is, from a regulatory point of view, more isolated than Norway. Were the UK to choose this option, changes would likely be considerably more extensive than in a soft exit. Additionally, a hard exit could lead to greater instability and fluctuations in financial markets.

The UK is currently working very hard to calm these concerns and convey that the UK will remain a powerhouse for life sciences. Indeed, the industry has been specifically cited as important for the UK by Prime Minister May during her initial days in office. That said, life sciences firms need to consider and prepare for all potential eventualities.

Opportunities and risks for clients to consider

As life sciences companies weigh their options, there are a number of opportunities and risks they should consider.

Commercial implications

When considering the commercial implications, life sciences companies will want to pay attention to six issues, both positive and negative, and plan accordingly:

1. **Currency.** Based on early reaction, there is every indication that Brexit will affect currency, particularly the pound, parallel trade, reference pricing and cost of goods for logistics. UK pharmaceutical companies are currently experiencing strong sales. Pharma giants such as AstraZeneca (AZ) and GlaxoSmithKline (GSK) are benefiting from the weaker pound. Should the pound's weakness continue post-Brexit, we expect strong sales to continue. Further, a decrease in the size of the parallel trade market will give UK manufacturing sales an additional boost. Although a low British pound may help boost sales revenues, there may be risks around reference pricing. A hard exit could negatively affect the UK's ability to obtain discounted drug prices, which would ultimately have a global effect on prices.

2. **Parallel trade.** The amount of prescription drugs imported through parallel trade into the UK will likely decline under Brexit, adding another pricing unknown as the UK renegotiates trade relationships with the EU.

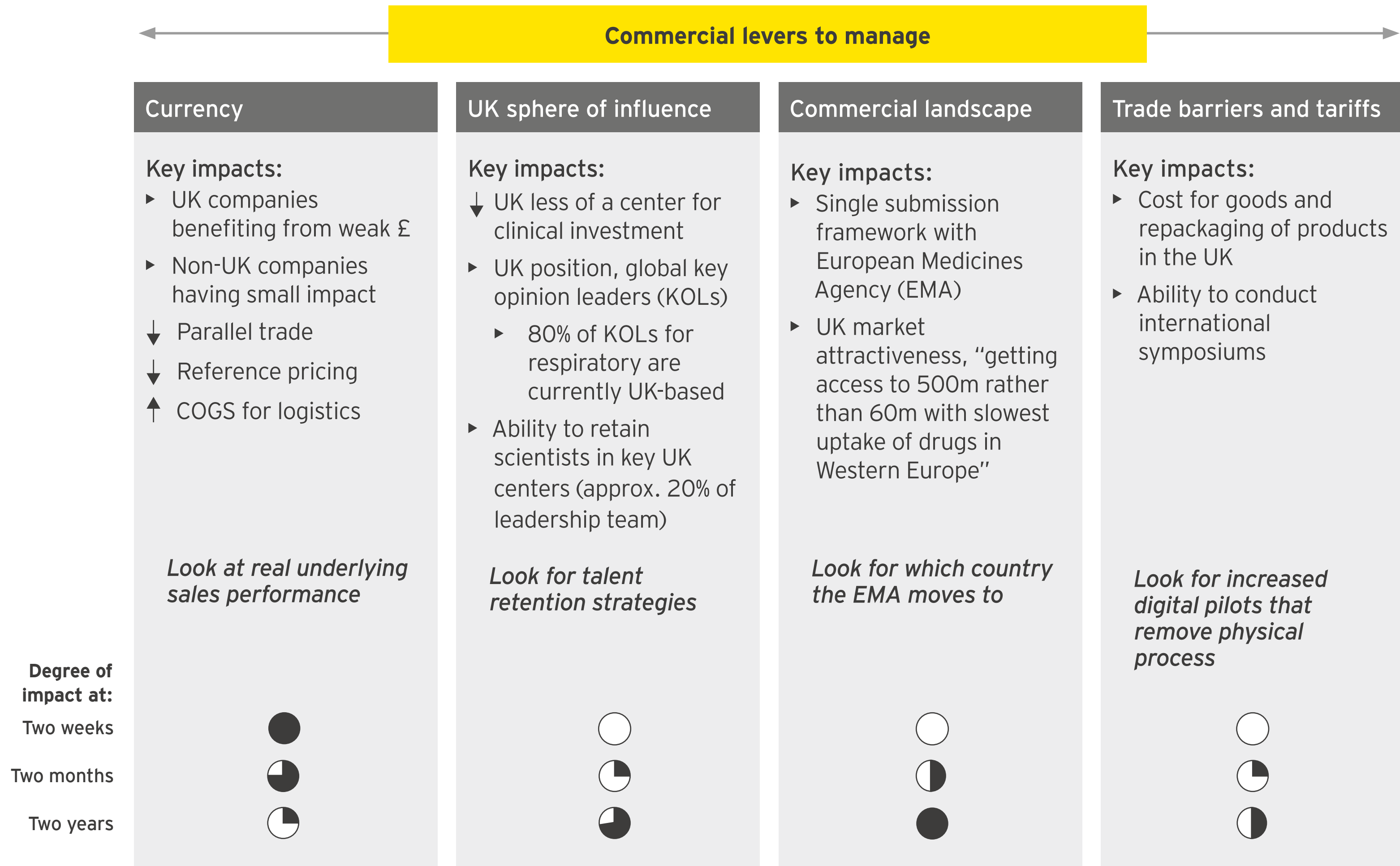
3. **Reference pricing.** UK prices are used as a reference for a number of other EU countries. Setting prices in pounds for new product launches may negatively impact the price of medicine in other countries.

4. **Trade tariffs.** In terms of trade tariffs, although a tariff isn't likely on actual medicines, primary ingredients could be subject to trade restrictions. This, as well as tariffs on packaging, would have the effect of making UK products — pharma and otherwise — more expensive.

5. **Drug launches.** The European Medicines Agency (EMA), currently headquartered in London, enables pharmaceutical companies to go through a single approval process, reducing the cost of drug approvals significantly. Under a hard exit, pharmaceutical companies would likely have to revert to seeking approval through the Medicines and Healthcare products Regulatory Agency (MHRA), on a country-by-country basis, which will require considerably more time, effort and resources.

6. **Human capital.** Commercially, the most predominant difference between a hard and soft exit, and the distinction that life sciences companies need to focus on, is that with a soft exit, people will still be able to move freely across borders. Under a hard exit, they will not. Rather, it puts thousands of people in a position of having to move to new countries. Not only will this have a direct impact on current employees of life sciences companies, but the UK's sphere of influence and its ability to retain scientists in key UK centers will likely be diminished. Life sciences companies should take pains to keep employees feeling positive about being based in the UK during this time of uncertainty. However, they should also be formulating a people strategy for the next six to nine months and creating a team to investigate the issue of relocation. Given that moving is not the preferred course of action, life sciences companies would do well to focus on establishing a strong lobbying presence with the Government in an effort to avoid it.

When considering the commercial implications, life sciences companies will want to pay attention to six issues, both positive and negative, and plan accordingly.

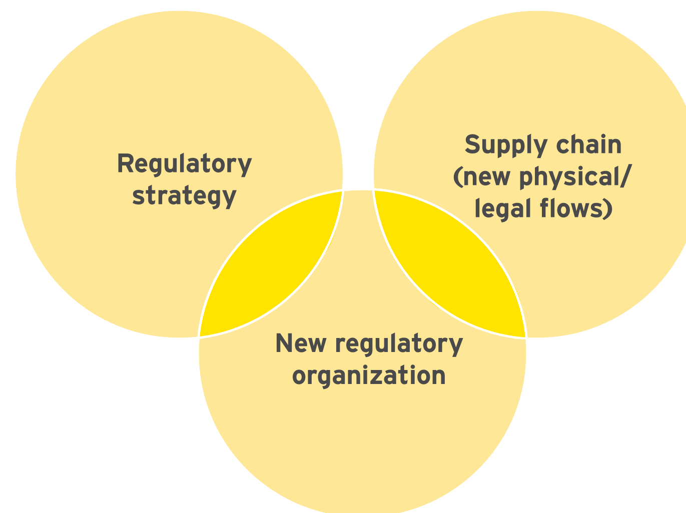

Commercial levers to manage
Currency
Key impacts:
UK companies benefiting from weak £
Non-UK companies having small impact
Parallel trade
Reference pricing
COGS for logistics
Look at real underlying sales performance
UK sphere of influence
Key impacts:
UK less of a center for clinical investment
UK position, global key opinion leaders (KOLs)
80% of KOLs for respiratory are currently UK-based
Ability to retain scientists in key UK centers (approx. 20% of leadership team)
Look for talent retention strategies
Commercial landscape
Key impacts:
Single submission framework with European Medicines Agency (EMA)
UK market attractiveness, "getting access to 500m rather than 60m with slowest uptake of drugs in Western Europe"
Look for which country the EMA moves to
Trade barriers and tariffs
Key impacts:
Cost for goods and repackaging of products in the UK
Ability to conduct international symposiums
Look for increased digital pilots that remove physical process
Degree of impact at:
Two weeks
Two months
Two years

Regulatory and legal requirements

From a regulatory and legal standpoint, life sciences companies will want to plan for and take action in the following areas:

1. **Regulatory strategy.** Because the EMA is currently headquartered in London, many international companies have positioned their European regulatory operations in the UK. In the event of a hard exit, the EMA will have to move, as will the regulatory European centers of many of these companies.
2. **Supply chain flow.** From a supply chain perspective, the physical flow of drugs between the UK and the EEA would be deemed importing or exporting, requiring new operating licenses and quality controls.
3. **Regulatory organization.** Depending on what choices they make regarding regulatory strategy and supply chain, life sciences companies will likely need a new setup for their regulatory organizations. Specifically, they may need to move people. Additionally, companies will have to rethink their contractual agreements around pharmacovigilance (PV) and quality.

Regulatory questions to consider



Strategic

- Where should the sponsor of clinical trials be located?
- Which entity should apply for/hold the EU marketing authorizations?
- Where should the medical devices conformity assessment be carried out?

Organizational and contractual

- Where should the Qualified Person for Pharmacovigilance (QPPV) be located?
- What is the impact on PV and quality agreements?

Operational

- What is the impact on operating (import/export) licenses?
- What is the impact on quality controls?

4. **Clinical trials.** UK pharmaceutical companies may lose the benefit of a single process application for their clinical trials across Europe. If the UK chooses the soft exit option and remains part of the EEA, it may continue to retain the same benefits as Europe, meaning the centralized marketing authorization procedure will continue to apply, and drugs that have been approved in the UK will be approved across Europe as well. If, however, the UK opts for a hard exit, there may be additional controls that would have to be negotiated, which could slow regulatory approvals.

5. **IP rights, data privacy and contracts.** Contract implications will revolve around whether a Brexit clause would trigger termination. A significant question for life sciences companies is whether Brexit would be considered a material adverse change (MAC) clause in a transaction. In addition to renegotiating contracts, life sciences companies will need to think about the legal implications of IP rights (which could affect the parallel market) and data privacy.

Legal questions to consider

IP rights	Data privacy	Contracts
Will the exhaustion of rights principle continue to apply? If not, what is the impact on parallel trade?	Will the UK be an "adequate jurisdiction"? If not, what is the impact on cross-border transfers?	Are there any "Brexit" or similar clauses triggering termination rights?
Where should the company locate the team in charge of prosecution and maintenance of the EU trademarks portfolio?	Where should the company locate the "Main Establishment" under the new EU Data Protection Regulation?	Which clauses are to be reviewed in UK-UK/UK-EU contracts?

Tax considerations

In terms of tax considerations, there are four broad areas life sciences companies should be thinking about to plan accordingly.

1. **Tariffs and trade:** In the life sciences sector many products are not subject to customs duty, and VAT is not usually a cost provided that it is properly managed. There may, however, be an increase in compliance costs in terms of customs declarations and formalities as products cross between the UK and the EU.

2. **Intra-EU tax reliefs:** A number of EU directives currently allow payments to be made between companies in different EU countries without incremental tax cost. Companies will need to review whether a hard or soft option would affect the tax treatment of such payments coming into the UK. In many cases, bilateral tax treaties exist between individual countries, and those may remove some, but not necessarily all, of the tax costs. As a result, these treaties may need to be reviewed on a case-by-case basis.

3. **Tax policy:** Given that the UK will want to continue promoting investment, we expect to see an increase in tax incentives. Before his resignation, the Chancellor of the Exchequer, George Osborne, pledged to lower the UK corporate tax rate o below 15%. We expect the UK to continue to be very much open for business as an R&D and commercial hub for the life sciences sector.

4. **Tax consequences of business restructuring:** Whenever business change happens, whether as a response to Brexit or otherwise, the tax consequences need to be considered. For example, when assets such as marketing authorizations are transferred, could there be a tax cost to doing this? If hedging arrangements are being put in place to manage foreign exchange volatility, are these arrangements effective post tax? Whenever significant people or functions move to a new location, thought needs to be given to whether this could give rise to a taxable presence in that location or whether that affects access to tax incentives changes.

Adapting capital and transaction strategies to new uncertainties

Brexit has added a new layer of complexity to management decision-making around the UK and the EU. Brexit has also amplified the headwinds clients have already been facing. There are, however, some critical considerations that companies need to keep in mind from a capital strategy perspective.

Brexit uncertainties

- Trade terms
- Tax policy
- R&D costs, access
- Talent mobility
- Foreign exchange rates, volatility
- Exit contagion (UK, EU)

Geopolitical and macroeconomic uncertainties

- Banking system stress (Italy)
- Growth outlook for emerging markets, particularly China
- Global trade/protectionism
- US elections

Business model disruptors

- Scientific and medical progress
- Payer pressures on prices and contingent contract structures
- Fourth industrial revolution: digitalization, analytics, AI, IoT, robotics

Core life sciences M&A drivers

- Growth imperative
- Strategic focus
- Scale and consolidation

Transaction enablers

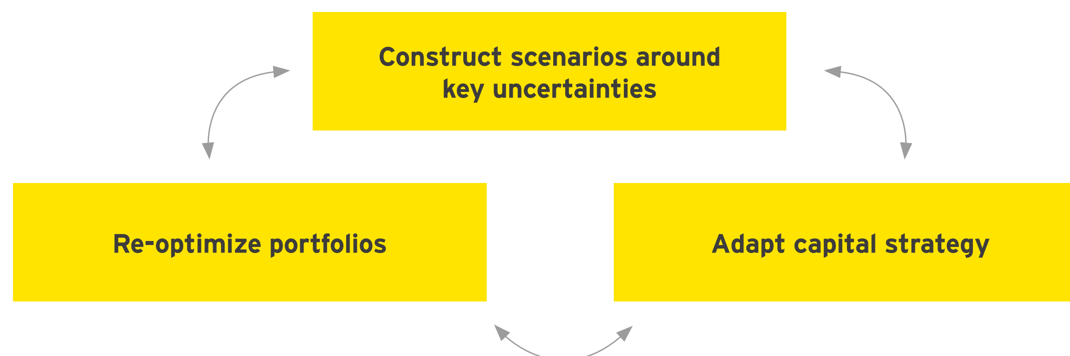
- 5 C's: confidence, cash, credit, currency, competition
- Shareholder scrutiny

Preparing to play offense and defense

1. **Rigorous scenario planning.** In addition to considering the "hard" and "soft" landing possibilities outlined above, managers need to prepare for additional uncertainties. While capital markets currently appear to view the primary Brexit effects as localized to the UK, cascading possibilities such as additional EU country exits, Scotland's secession, and prolonged banking system stress must be addressed. Another example: consider the implications for bilateral UK-US trade agreements with a US electorate increasingly suspicious of free trade.

2. **Re-optimizing business, therapeutic area and geographic portfolios.** Increased uncertainty and divergent growth rates across major markets means the relative attractiveness – based on strategic fit and financial metrics – has changed for many portfolio elements. Companies should refresh their performance outlook across the portfolio and update their *divestiture watch list* of assets that no longer make sense to own. Conversely, depressed valuations and exchange rate moves may provide new opportunities to *acquire* the right targets to bolster existing capabilities and position for a reconfigured European playing field post-Brexit. The referendum's aftermath may also have altered the feasibility of pending transactions so new "white knights" may appear.

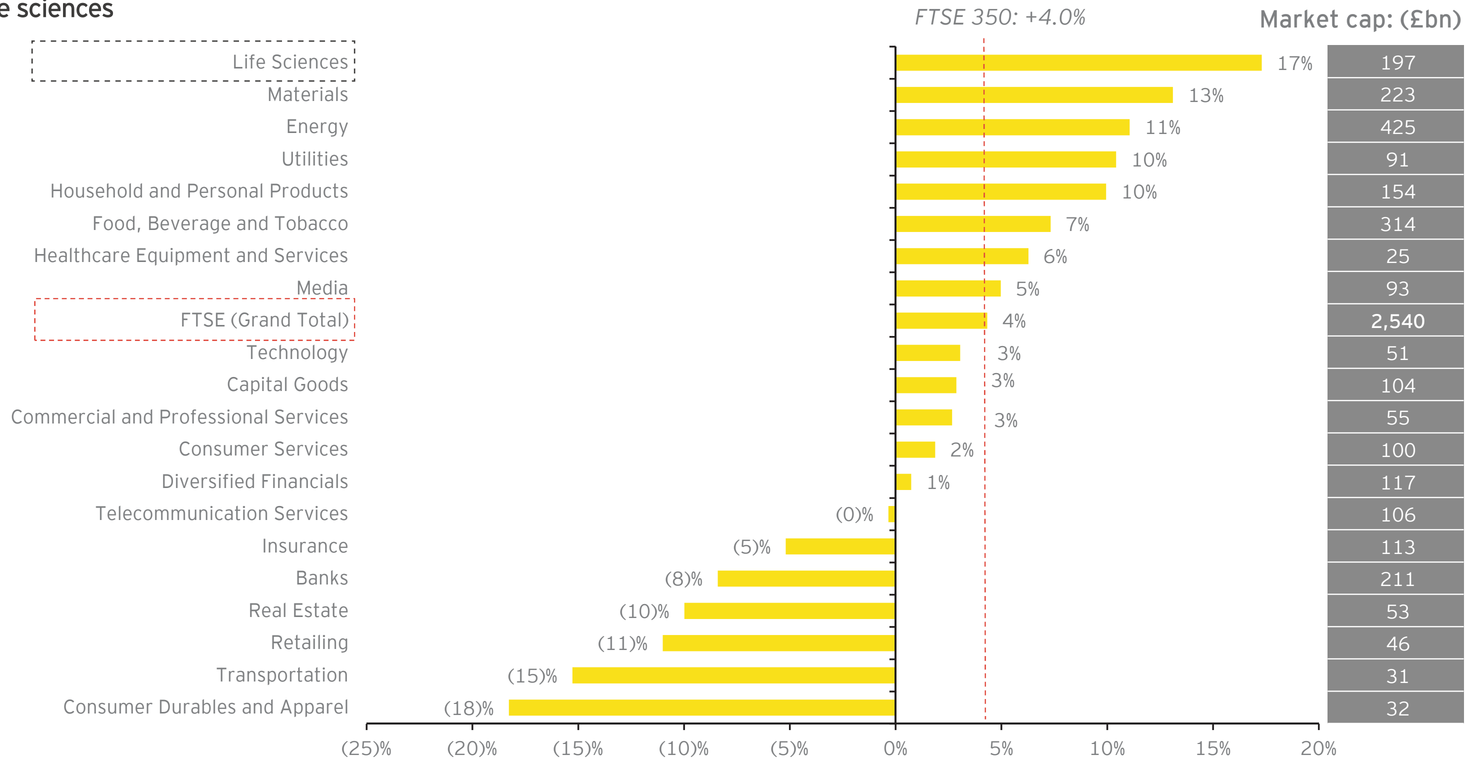
3. **Adapt capital strategy and financial planning.** While treasury groups will already be busy adjusting currency hedges and rethinking optimal capital structure, managements need to reconsider dividend and share repurchase policy. For example, increased uncertainty and a fragmented European market may require less leverage, additional cash cushions and more working capital. Investors will need comfort that risks are being managed as well as assurance that opportunities are being pursued aggressively.



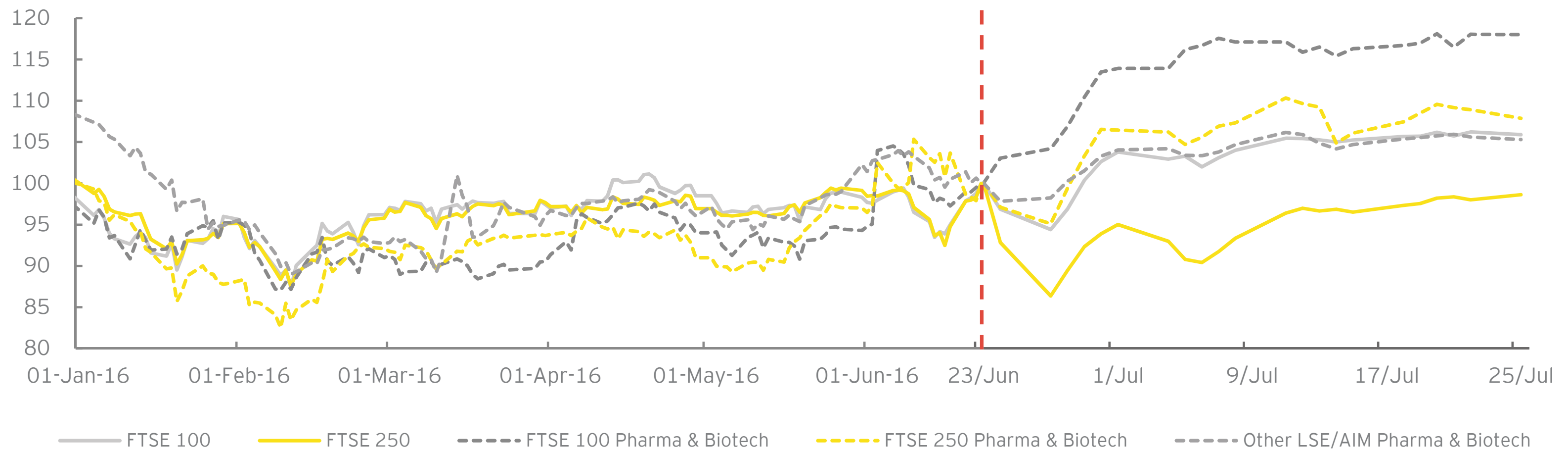
Management workstreams

- Three of four robust scenarios
- Competitor analysis
- Counterparty risk assessment of creditors and partners
- Financial plans, including foreign exchange hedging and revamping capital structure
- Acquisition wish list
- Divestiture watch list
- Communication plans for investors, employees and partners

Life sciences is the strongest performing UK sector since the referendum

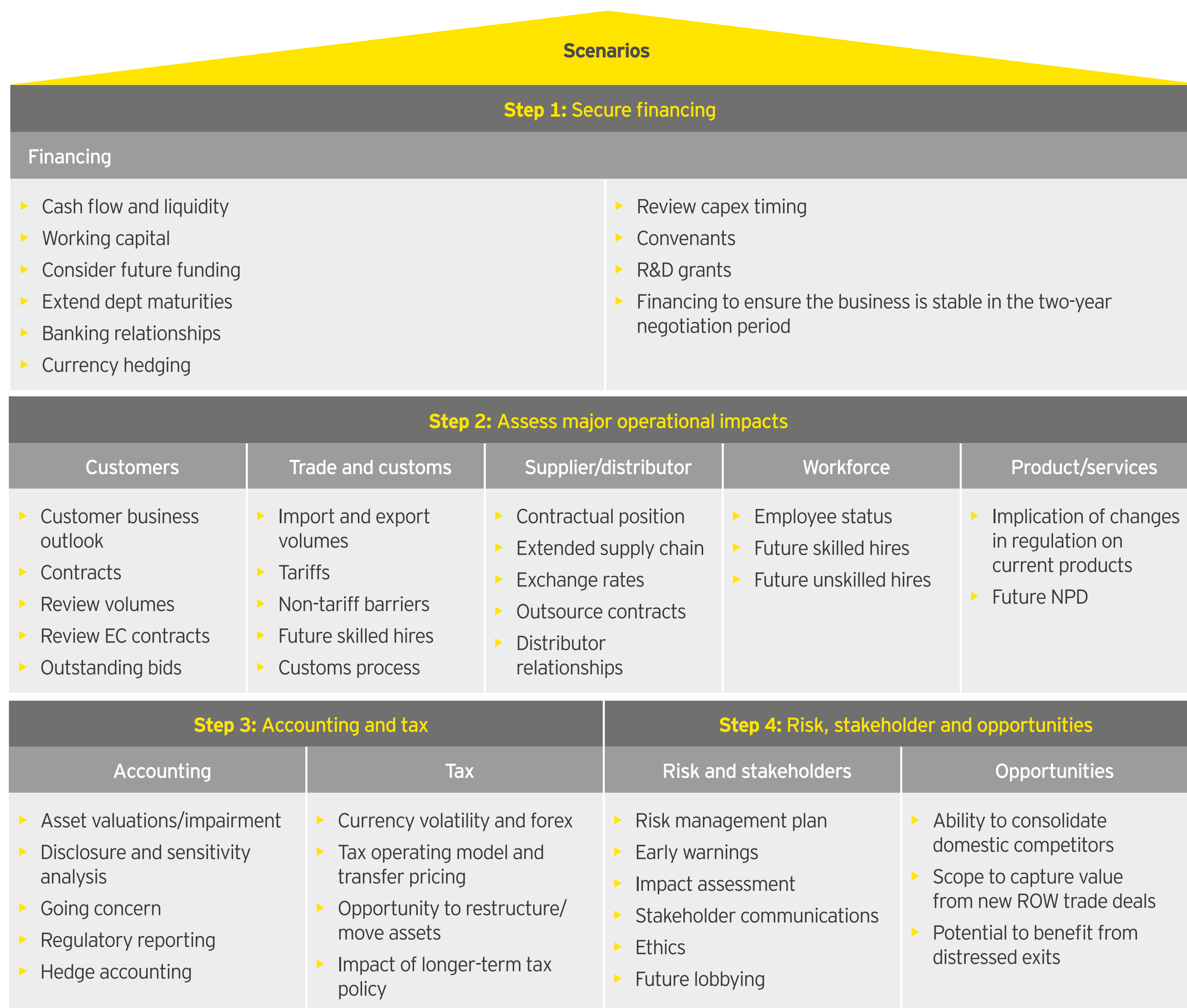


Biopharma constituents have outperformed their FTSE indices



Equity market movement indexed to 23 July 2016

Bringing it all together – enterprise wide scenario planning, accessing commercial impact and plan for success



Digital disruption

Although the acceleration of digital, analytics and the Internet of Things (IoT) are not Brexit-specific, they are areas to watch as Brexit unfolds. As digital technologies continue to disrupt business models, Brexit may present opportunities across the board, from increases in digital pilots that remove physical processes, thereby mitigating trade barriers and tariffs, to acquisitions that take advantage of the devalued British pound and boost digital capabilities.

Plan for all eventualities

As CEOs and their boards of directors consider both the opportunities and the risks that Brexit presents, they would be wise to study a number of scenarios. At a minimum, CEOs should be thinking about increasing their companies' flexibility, whether it's tax planning, supply chain or shared services. In the past, the trend was to become as lean and efficient as possible. But at a time when CEOs are unable to predict what a business or a geographic portfolio is going to look like one, three or five years from now, there needs to be trade-off between efficiency and flexibility.

The other key to navigating a successful Brexit strategy is to communicate. CEOs should be developing an open people communication strategy for the next six to nine months. This will mitigate very personal understandable fears. In such times of uncertainty, building a strong enterprise-wide "Brexit Trust quotient" is critical.

Ultimately, however, even as life sciences companies prepare for all eventualities, there is a reality that they will have to, at least on some level, follow the flow as the UK and EU negotiate their split and clarity appears. EY is in constant communication with regulators and tax authorities as we continue working closely with our clients.

All things considered, time should be taken to prepare

In the short-term, life sciences businesses should avoid knee-jerk reactions. Absent good data, decisions made in this period are as likely to be good as they are bad. The focus should be on shoring up the business and initiating the research and analysis to enable strategic and operational decisions as we learn more about what terms are negotiated by the UK Government and thus what precise form Brexit will take.

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How EY's Global Life Sciences Sector can help your business

Life sciences companies — from emerging start-ups to multinational enterprises — face new challenges in a rapidly changing health care ecosystem. Payers and regulators are increasing scrutiny and accelerating the transition to value and outcomes. Big data and patient-empowering technologies are driving new approaches and enabling transparency and consumerism. Players from other sectors are entering health care, making collaborations increasingly complex. These trends challenge every aspect of the life sciences business model, from R&D to marketing. Our Global Life Sciences Sector brings together a worldwide network — more than 7,000 sector-focused assurance, tax, transaction and advisory professionals — to anticipate trends, identify their implications and develop points of view on responding to critical issues. We can help you navigate your way forward and achieve success in the new ecosystem.

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