Navigating the perfect storm
Impact of political, tax and regulatory change on European life sciences supply chains
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1. Introduction

A confluence of political, tax and regulatory changes during the next 2-5 years will reshape both the physical and financial flows that underpin life science companies’ European supply chains. The impacts are likely to be far reaching but will ultimately depend on each company’s unique circumstances. This paper identifies some potential risks as well as actionable steps that companies can take now regardless of how events unfold.

Recent political events have created an unprecedented level of uncertainty for the life sciences industry and global economy alike. In June 2016, the UK population voted in an historic referendum to leave the European Union; in November 2016, the United States selected Donald Trump as their 45th President. It is still too early to fully appreciate the long-term implications for these moves for global free trade and the migration of people. One of the principles laid out in Theresa May’s Article 50 letter informing the European Council of Britain’s intention to leave the European Union is that UK rejects the free movement of people and therefore does not seek ongoing membership of the European Single Market post Brexit. Early executive orders from President Trump point to a more protectionist stance for the US, albeit with the prospect of tax reforms that have the potential to be more favourable to US multinationals with substantial US based operations.

In parallel with these political developments, individual countries are continuing to implement global tax measures that resulted from the 2012 Organisation for Economic Cooperation and Development (OECD) led Base Erosion and Profit Shifting (BEPS) initiative. BEPS is driven by a need to modernise global tax rules to deal with the modern globalised economy, improve transparency and prevent profits being artificially shifted to low or no-tax locations. Life sciences companies whose supply chains include operations such as principal trading companies, toll manufacturing and ownership of inventory in a second country will need to evaluate those operations in light of BEPS.

At the same time, life sciences regulatory change continues apace. One regulation that is expected to have a significant impact on the shape of European supply chains is Annex 21. The aim of Annex 21 is to clarify EU Good Manufacturing Practice (EU-GMP) requirements applicable to importers of medicinal products to the EU. This includes establishing a common understanding of the term ‘import’, particularly where there is some complexity in the physical and financial flows.

This paper draws on insights from Deloitte’s life sciences consulting, regulatory and tax practitioners. Utilising representative supply chain archetypes for EU, US and Switzerland headquarteried life sciences companies, it explores the forces that have the potential to reshape European life science supply chains. We identify some potential ‘red flags’ and present some ‘no-regret’ actions that life science companies should consider now.

The paper is intended as a point of view to stimulate discussion and debate. We welcome your feedback.
2. Forces reshaping European life sciences supply chains

The political, tax and regulatory changes that have the potential to reshape European life sciences supply chains during the next 2-5 years are summarised in Figure 1.

We have based our analysis on what we believe to be the most likely outcome in each of the four areas. Specific notes and assumptions on each area include:

- **BEPS** – On 5 October 2015, the OECD published 13 final reports and an explanatory statement outlining consensus actions under the base erosion and profit shifting (BEPS) project. The G20 and OECD continue to finalise a number of areas, and at the same time individual countries are now in the process of implementing domestic legislation to reflect the BEPS actions. Our assumption is that the countries that have signed up to the BEPS project will implement domestic legislation to reflect the main BEPS recommendations, including signing up to the Multilateral Instrument as an innovative approach to amend bilateral tax treaties.

- **Brexit** – For this analysis we have assumed a ‘hard Brexit’ with the UK leaving both the European Single Market and the European Union Customs Union. We firmly believe that there are compelling reasons on both sides to reach a mutual recognition agreement between the UK and EU regulators (MHRA and EMA); however, we assume in this analysis that this is not achieved and that products produced in the UK as a third country need to be both import tested and certified by a Qualified Person (QP) located in an EU country (and vice-versa).
• **EU-GMP Annex 21** – In the absence of the final draft, our assumption is that Annex 21 will adopt and make standard across the EU, the import definition that was introduced by the Belgian health authority (FHMAP) in 2013. Under this definition, an import occurs where title passes from a non-EU (third country) organisation to an organisation within the EU, even if the product has not physically moved. As an import is classed as a manufacturing operation, the site holding inventory will now require a Manufacturing Import Authorisation (MIA). This also potentially means that a QP certification with all necessary quality management systems will be required for each such change in title. Trading models with flash title transfers involving a third country and possibly Switzerland will therefore need to be reviewed.

• **US Tax Reform** – The Trump administration is advocating a once in a generation tax reform to address a tax system that is increasingly uncompetitive when compared among advanced countries. Our assumption is that US corporation tax will be cut and that US based life sciences companies may take the opportunity, in the short-term, to repatriate profits held offshore and longer term to review their supply chain and legal structures, which may mean increased value creating activity being located in the US, and therefore increased profits being generated in the US. Life sciences companies may also need to adapt to a proposed Border Adjustment Tax, which could also create incentives to locate a greater proportion of value adding activity on US soil.

The paper is intended as a point of view to stimulate discussion and debate. We welcome your feedback.
3. Common European supply chain archetypes

The degree of impact and opportunity that these combined political, tax and regulatory changes present depends on each life science company's unique circumstances. However, it is possible to identify potential ‘red flags’ that will require greater attention and to draw some high level conclusions and suggested actions for some common European supply chain structures.

In this section, we present three common supply chain archetypes. In our experience most real-world life science supply chains are highly complex and exhibit some form of hybrid of these archetypes and therefore the insights generated for each will be of interest to many life sciences companies.

**Figure 2. US multinational with Swiss principal trading structure in Europe (A)**

In Figure 2 we depict a supply chain archetype that is common with US based biotechs that hold marketing authorisations in the EU but have a limited physical presence. In this tax-efficient model, a principal trading company is commonly located in a lower tax country – often Switzerland, but it can be Ireland or others. The principal holds title to inventory and operates through a Commissioner or Limited Risk Distributor (LRD) model in other European countries. Profit is distributed (and taxed) on the basis that the principal bears full market and inventory risk while in-market activities are considered to be routine in nature, auxiliary or preparatory.

Product will typically be imported from the US or other third countries through an EU based hub that holds a Manufacturing Import Authorisation (MIA). The hub ensures that EU import testing and other EU-GMP requirements are met prior to QP certification. It is possible that in the timeframe of this analysis that the need for or role of such an EU hub could change due to the EU and US Mutual Recognition Agreement (MRA) signed in February 2017, one outcome of which is the possible waiving of the requirement for testing of US imports following a two year transition period.
Where further manufacturing or finishing steps are required within Europe, this is often conducted through a toll arrangement with either the US HQ or European principal acting as the toll principal.

The current US tax structure makes it unattractive for US companies to repatriate profits that build up in the European principal. Profits are therefore held or permanently reinvested outside of the US.

**Figure 3. EU multinational (B)**

Major EU based multinational life sciences companies typically have mature international operations, often with greater than 50 per cent of sales generated outside of Europe in the US, Asia Pacific and emerging markets.

EU multinationals, like US multinationals, may employ tax efficient financial structures such as a principal trading company structure; however, for the purposes of this analysis, we assume that physical and financial flows are aligned through buy-sell transactions with local country affiliates or distributors. The US market will typically be supplied with drug substance or drug product for subsequent finishing in a US based facility.

In this model, profit is distributed through intercompany transactions, which aim to reward intellectual property (IP) owning locations or other locations where significant centralised activity takes place such that the organisation’s residual profit ends up in those locations. Entities in other countries that support the organisation’s supply chain often perform limited risk activities for the organisation and are remunerated accordingly.
As these companies are typically operating at scale within the EU, they will hold multiple MIAs and will be capable of testing and releasing product from multiple EU locations for onward distribution within the EU and globally.

Note that when analysing the implications of Brexit and US Tax Reform we will need to distinguish between a UK and other EU country headquartered company.

**Figure 4. Swiss multinational (C)**

Figure 4 is a representation of a Swiss headquartered major life sciences company. In this model, the Swiss HQ acts as a principal trading company within Europe and, like the US multinational model, it holds title to inventory and operates through a Commissionaire or Limited Risk Distributor model in other European countries. The Group’s residual profits arise in Switzerland and are subject to a favourable tax regime.

Switzerland sits outside of the EU and EEA; however it holds the status of Mutual Recognition Agreement (MRA) Partner Country rather than third country. EU-GMP therefore recognises Swiss manufacturing authorisations and manufacturers’ certificate of conformity without retesting on import. However, the QP of the ‘official importer’ in the EU must still assess if GMP requirements have been met on first import of a batch to the EU before releasing and tracking products during further distribution and sale.
The degree of impact and opportunity that the forthcoming political, tax and regulatory changes present depends on each life science company’s unique circumstances.
**Impact and opportunity analysis**

The table summarises the impact and opportunity for each supply chain archetype.

<table>
<thead>
<tr>
<th></th>
<th>BEPS</th>
<th>EU-GMP Annex 21</th>
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<tr>
<td><strong>A. US Multinational with Swiss principal trading structure in Europe</strong></td>
<td>BEPS is creating significant regulatory change that may require US multinationals to restructure their supply chains to avoid adverse tax consequences. BEPS will in the future increase the risk that inventory owned by a Principal company and physically stored in a second country creates a taxable presence for the Principal in the country where the inventory is stored. Trading models that increase risk include Commissionaire structures, structures that include centralised warehouses, limited risk distributor and/or toll manufacturing entities. To manage this additional tax risk, multinational groups may seek to realign the ownership of inventory to transfer ownership to the local sales companies, and they may also consider changing how inventory is stored and managed. The transfer pricing comments below are also relevant for US multinationals.</td>
<td>Under Annex 21, a change in inventory title within the EU involving a third country will be regarded as an import and the inventory holding site will require an MIA and QP certification may also be required. It is not clear if Switzerland would be regarded as a third country in this context; however, if this is the case, flash title transfers involving a Swiss principal will need to be reviewed. One possible solution is that companies move towards a buy-sell inventory title transfer model with in-market partners. i.e. this may bring companies to a similar conclusion to BEPS.</td>
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<tr>
<td><strong>B. EU Multinational</strong></td>
<td>Similar to US multinationals, EU multinationals are responding to significant regulatory change that is being driven by BEPS. EU multinationals will also need to manage changes in their supply chains to avoid creating additional permanent establishments, particularly where inventory is stored in central warehouses and where the product stored in those warehouses is sold into additional countries. The BEPS agenda is also placing an increased focus on transfer pricing of intercompany transactions and multinationals will need to carefully review their end to end supply chains to ensure that the activities performed by each legal entity are appropriately remunerated in the post BEPS landscape.</td>
<td>Limited impact for EU Multinationals operating in Europe without a principal trading structure.</td>
</tr>
<tr>
<td><strong>C. Swiss Multinational</strong></td>
<td>Swiss companies need to manage similar challenges to EU multinationals as a result of BEPS. In addition, Swiss companies are anticipating significant Swiss tax reform that will also have to be considered.</td>
<td>Unclear whether the new Annex will differentiate between a third country or an MRA Partner Country. If no differentiation then impact will be the same as for the US Multinational scenario.</td>
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### Brexit

Companies whose main EU import hub is located in the UK will potentially be required to conduct import testing and product release in the UK and again on subsequent distribution to an EU country. They may also incur tariffs on exports from the UK to countries where tariffs had previously been eliminated.

Companies with import hubs located in another EU country will face a similar issue in reverse when exporting product to the UK; however, overall volumes and hence impact should be substantially reduced. Companies with a UK based EU import hub should therefore consider relocating the EU part of the import hub operation to another EU country.

In the short-term, the risk of UK/EU tariffs should drive companies to minimise the value of UK/EU product flows. However, the UK government has signalled an openness to free trade agreements with countries outside of the EU post-Brexit. Such trade agreements are likely to take many years to finalise.

QP or import testing activities located in the UK supporting product certification in EU countries will need to be reviewed and likely mirrored in an EU country.

### US Tax Reform

Whilst the detail of US tax reform remains unclear, the impact of the proposed changes could be dramatic and could lead to a significantly more competitive US tax landscape being introduced.

A more competitive US tax landscape may make it attractive for US multinationals to relocate certain activities to the US. As the business models of US multinationals evolve global supply changes will need to be adjusted to align with the new business models that may be driven by US tax reform.

US Tax Reform may include the introduction of a Border Adjustment Tax that could compel EU based life sciences companies to re-evaluate how they supply the US market. This could mean reducing the value of product flows into the US and potentially establishing a larger footprint of drug substance and drug product manufacture as well as finishing operations in the US.

A post-Brexit UK/US trade deal that is favourable in terms of tariffs and country of origin rules may position the UK as a hub for European exports to the US.

As for the other scenarios, UK based EU QP and import testing activities will need to be reviewed and likely relocated, at least in part.

Swiss companies are likely to need to manage similar challenges to EU multinationals as a result of US tax reform.
4. Navigating the perfect storm

The timings and impacts of the emerging political, tax and regulatory changes will overlap, however, life sciences companies should not expect any level of coordination between them. Those companies that have considered and prepared for what this means for their supply chains in a holistic sense will be best positioned to maximise business value.

In this section, we outline four areas that we believe life sciences companies can usefully focus on today to align and prepare the organisation to reshape the supply chain.

1. Understand the impact of external changes and map trade flows

While some uncertainty remains, the implementation of Annex 21, BEPS, US Tax Reform and Brexit are all likely to create regulatory changes that will impact the financial efficiency of supply chain structures for life science companies. For example, with the implementation of BEPS, companies will need to determine whether they have the appropriate level of substance4 in each territory to justify current trading models and transfer pricing structures. Similarly, the potential for trade tariffs between the UK and the EU Single Market and the proposed US Border Adjustment Tax will require the trade flows between those territories to be re-examined with a view to minimising customs duties and broker charges.

To help understand the financial impact of changing effective tax rates and trade tariffs, we recommend that companies begin with mapping their value chains and overlaying the impact of different regulatory change scenarios.

One way to approach this is to use a tool such as Deloitte’s Value Chain Analytics Tool, which enables companies to visualise how profit is allocated throughout the value chain. As part of this value chain mapping process, companies should catalogue instances such as toll manufacturing and limited risk distributors where inventory is stored in one country but legally owned by an entity in another; looking out in particular for inventory located in the EU with title in a third country, which raises potential ‘red flags’ from both a BEPS and an EU-GMP Annex 21 perspective.

We also recommend that companies undertake a customs data analysis to understand key trade flows between the UK and EU markets and other key global flows particularly US imports. Deloitte has developed a Customs Data Analyser that extracts these data from enterprise systems and provides an analysis of transactions, commodity codes, customs value and duties paid and is able to model the impact on duties and broker charges for different customs scenarios such as a ‘most change’ scenario of the UK adopting World Trade Organisation trading terms post Brexit.
2. Explore solutions and opportunities
There is some short-term uncertainty in terms of the combined political, tax and regulatory impact on supply chains. However, there is useful groundwork that companies can undertake now to prepare for different eventualities. We recommend that supply chain leaders partner with their tax and regulatory colleagues to develop and analyse scenarios, identify feasible solutions and seek opportunities to, for example, reduce complexity and streamline operations.

Companies should focus first on any ‘red flags’ that are identified during a value chain assessment. These will include trading relationships such as toll manufacturing and limited risk distributors. There are multiple options that companies may evaluate to, for example, reduce the possibility of establishing permanent establishments. However, for many of these options, companies will be dependent on the willingness and capability of third parties to operate in a different way. It is therefore important to engage early to understand what is feasible, the impact on costs and what steps would be needed to implement.

Life sciences companies may also be compelled through the introduction of new trade tariffs and the proposed US Border Adjustment Tax to consider relocating manufacturing operations. Companies should therefore undertake internal and external analyses of manufacturing capability and capacity to understand both short and long term options and transition plans.

Other areas worth exploring and bringing up to date include:

- mapping Marketing Authorisation Holders (MAH), QPs, MIAs and the network of quality agreements that underpin global product manufacturing and distribution operations; and

- evaluating the potential impact of Brexit and new toll manufacturing and limited risk distributor trading relationships on VAT flows and working capital.

3. Manufacturing and supply chain network strategy
Decisions that supply chain leaders make today in establishing manufacturing capacity and designing supply chain networks have long term implications. It is not unusual for these decisions to be made in collaboration with tax and regulatory functions; however, this is now more important than ever. We recommend that life sciences companies take the opportunity now to review existing or develop new manufacturing and supply chain principles that guide and shape future supply chain design. Some example new principles could include:

- minimise value of US imports in the event that the Border Adjustment Tax is introduced;

- review and, if necessary, reconfigure supply chains to minimise transfers between the UK and Europe until it becomes clear where UK/EU and other country post Brexit trade deals are heading; and

- locate EU Marketing Authorisation Holder (MAH), import testing and QPs outside of the UK.
4. Consolidate impacts on product labelling

EU-GMP Annex 21 is an important regulation in terms of clarifying and harmonising the requirements applicable to importers of medicinal products to the EU. However, it is one of many regulatory changes that life sciences companies are preparing for. Figure 5 is a summary of the regulation timelines relevant to life sciences companies operating in Europe.
From a supply chain perspective, artwork and labelling is a key area where many of these regulatory changes overlap and can often be a bottleneck for organisations seeking to optimise their supply chain network. Companies need to coordinate their response not just from a regulatory perspective but also working closely with tax and supply chain colleagues. We recommend establishing finished goods stock keeping unit (SKU) level plans that bring together a single overview of political, tax and regulatory driven labelling changes with the goal of minimising regulatory workload and complexity. Plans should include:

- the possibility of UK specific labelling post Brexit;
- Market Authorisation Holder (MAH) transfers; and
- planned changes to manufacturer or country of origin.

Companies need to coordinate their response not just from a regulatory perspective but also working closely with tax and supply chain colleagues.
Conclusion

The confluence of political, tax and regulatory changes during the next 2-5 years will reshape both the physical and financial flows that underpin European life sciences supply chains.

Companies answering ‘yes’ to any of the following questions will be impacted to some extent and will need to take action. As a multi-national company, do you have:

- Complex physical and financial flows involving a principal trading company structure, toll manufacturing or limited risk distributors
- Inventory title transfers within the EU involving a company based in a third country
- US headquartered operations employing principal trading structures in Europe
- EU import hub, import testing operations or QPs located in the UK
- High value imports to the US or significant trade flows between the UK and other EU countries.

The degree of impact and opportunity that the forthcoming political, tax and regulatory changes present depends on each life science company’s unique circumstances. Those companies that have considered multiple scenarios and prepared for their eventual outcomes in a holistic sense will be best positioned to maximise business value. Whilst there is still likely to be a great degree of uncertainty over the next few years as companies navigate this perfect storm, the recommendations highlighted in this report are actions that companies can take now regardless of how events unfold.

Companies that have considered multiple scenarios and prepared for their eventual outcomes in a holistic sense will be best positioned to maximise business value.
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Endnotes

1. A Qualified Person (QP) is named on a manufacturer’s authorisation as legally responsible for certifying that each batch of a medicinal product is suitable for release for sale or for use in a clinical trial within the EEA.

2. A Commissionaire sells to customers and acts in the commissionaire’s own name; however, it is the principal that is contractually bound to deliver goods to the customer. No contractual relationship is created between the customer and the principal.

3. A Limited Risk Distributor (LRD) distributes products in its own name and for its own account for a principal company under an arrangement in which most risks are borne by the principal and only limited risks are borne by the LRD.

4. Substance is defined as DEMPE (Development, Enhancement, Maintenance, Protection and Exploitation) in the OECD’s BEPS documents.