
# PHARMACEUTICAL DISTRIBUTION

## KEY SUPPLY CHAIN CHALLENGES 2019

This strategy paper provides an overview of some of the key supply chain challenges facing pharmaceutical companies in the year ahead, 2019.

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**"In recent years the pharmaceutical industry has faced increasing challenges due to patent expiries and pressures on government national healthcare spending – this will continue."**

## 1. Introduction

On November 1st, 2018, to stave off cheaper competition, AbbVie slashed its biggest selling drug Humira's European price tag by 80% (source: 'AbbVie offers up 80% Humira discount in EU tender market to hold off biosimilars': report Fiercepharma). Its share price reacted with a fall of over 4%. The fall in its share market price had long been anticipated as Humira makes up more than 60% of the company's revenue. Fortunately, the company was able to control much of the damage as manufacturing costs of Humira are relatively low. The margin decrease is set to continue in the years ahead as the US market comes off patent in 2023. In the industry, there is a whole list of other big selling drugs owned by other large pharmaceutical companies which will come off patent in the coming years (source: 'Patent expiry dates for biologicals: 2017 update', GaBI Journal).

In recent years the pharmaceutical industry has faced increasing challenges due to patent expiries and pressures on government national healthcare spending which we won't have time to further discuss here. However, as a result of this, operating margins have come under increasing pressure. At the same time, it is increasingly expensive to develop and launch new medicines. Research & development costs have increased, and long R&D lead times make it a major challenge for existing players and even more so for start-up companies to find the funding needed to finance the development and the introduction of new medicines.

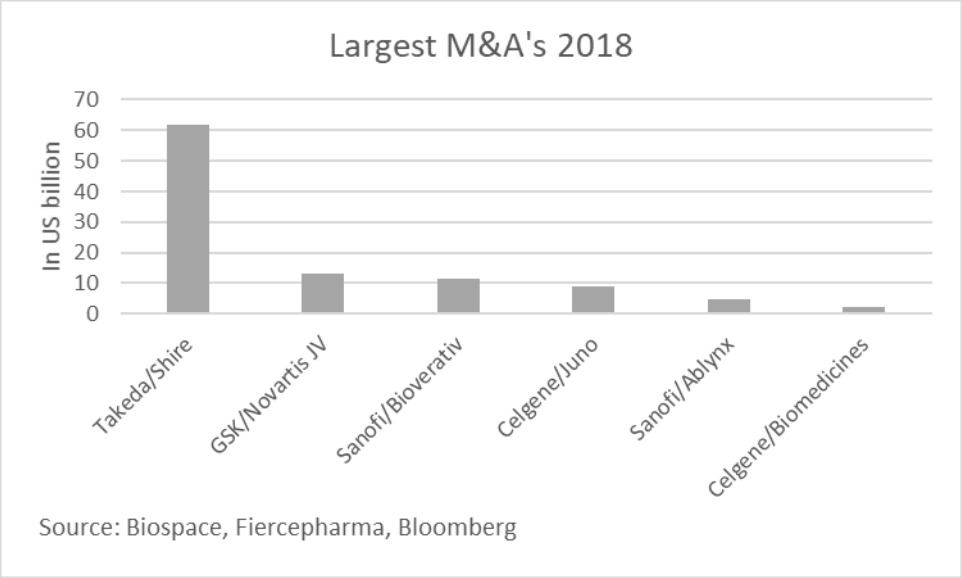
In 2018, big pharma companies have stepped up from the trend from before the financial crisis to again buy up other companies. There was much merger & acquisitions activity in 2018 (sources: 'Flurry of Activity: Top 2018 Biopharma M&A Deals So Far', Biospace and 'Pharma shells out $100B on M&A in 2018 so far, with more to come: report', Fiercepharma).

One such large deal involved French based Sanofi. In late-January, Sanofi acquired Waltham, Massachusetts-based Bioverativ for about US$11.6 billion. Bioverativ was a spinoff by Biogen. About a week later, Sanofi bought Ghent, Belgium-based Ablynx for

US$4.8 billion. Then, on April 17, Sanofi agreed to sell its generics division, Zentiva, to Advent International for about US$2.4 billion. Advent is a private equity firm.

Another prominent deal was Celgene Corporation's acquisition of Juno Therapeutics in January for about US$9 billion. This deal came shortly after Celgene's deal for Impact Biomedicines for US$1.1 billion upfront and US$1.25 billion in various milestone payments.

However, the biggest deal this year has been Japanese Takeda Pharmaceutical Co. who earlier this month received shareholder approval for its US$62 billion acquisition of U.K.-listed Shire (source: Bloomberg Dec 4th, 2018).




Following the trend from other sectors such as the automotive, fashion and electronics sectors, more and more pharmaceutical companies in the industry have chosen in recent years to outsource its manufacturing to external CMO's (contract manufacturing organisations). One important reason is that it allows pharmaceutical companies to focus their efforts on the development of new drugs on the one hand and on the other hand on the commercialisation (sales and marketing) of its products into the market.

The challenges which pharmaceutical companies face anno 2019 create new opportunities for logistics service providers operating in the upstream and downstream supply chain. This strategy paper seeks to explore some of these challenges. In turn these challenges provide opportunities to allow the industry in the area of supply chain and distribution to develop innovative solutions and collaborate more which pharmaceutical companies are increasingly open to explore.

One factor which is vital to how these challenges are best navigated is the role supply chain leadership plays within pharmaceutical companies.

Another factor which is on its way to revolutionize the value chain is the capability to interpret larger sets of data in order to take better and more factual based decisions. The digitalization of the supply chain, meaning the ability to access sets of data just-in-time across the end-to-end supply chain will enable best-in-class digitalized bio-pharmaceutical companies to gain commercial advantage over others. This is certainly a key aspect of the overall change which will take place in the coming years. Companies should invest now in their journey to supply chain digitalization to stay in the race.

We will explore these factors throughout this strategy paper.

# Key Challenges

Moving into 2019 pharmaceutical companies are faced with a continuous set of business challenges related to their upstream and downstream supply chain which are all potential drivers for change. We have summed up some of the key challenges in terms of 2 indicators: urgency and impact. These are:

- Pricing pressure impacting commercial models
- Cost pressures on manufacturing and sub-optimisation
- High inventory levels and safety stocks
- Fragmented supply chain (internal ownership and information deficit)
- Big data. Digitalisation of the supply chain
- Serialisation requirements
- Corporate Responsibility. Reduction targets related to CO2 emissions
- Impact of Brexit on current business across EU and UK

| **Strategic Challenges** | **Urgency** | **Potential Business Impact** |
|---|---|---|
| | | |
| Commercial Pricing pressure | High | High |
| Operational Cost pressure | Medium | High |
| Inventory Costs | Medium | High |
| Fragmented Supply Chain | Medium | High |
| Big Data | Medium | High |
| Serialisation Requirements | High | High |
| Corporate Responsibility - CO2 Footprint | High | High |
| Brexit Impact | High | High |

# The Commercial Model & Big Data Gap

### 1. Pricing Pressure Impacting Commercial Models

This seems like kicking the same can over and over again. However, pricing pressure facing the industry has still not resulted in sufficient pressure within companies to face the reality of reducing their cost base, organisational costs and gross margins in an increasingly competitive market.

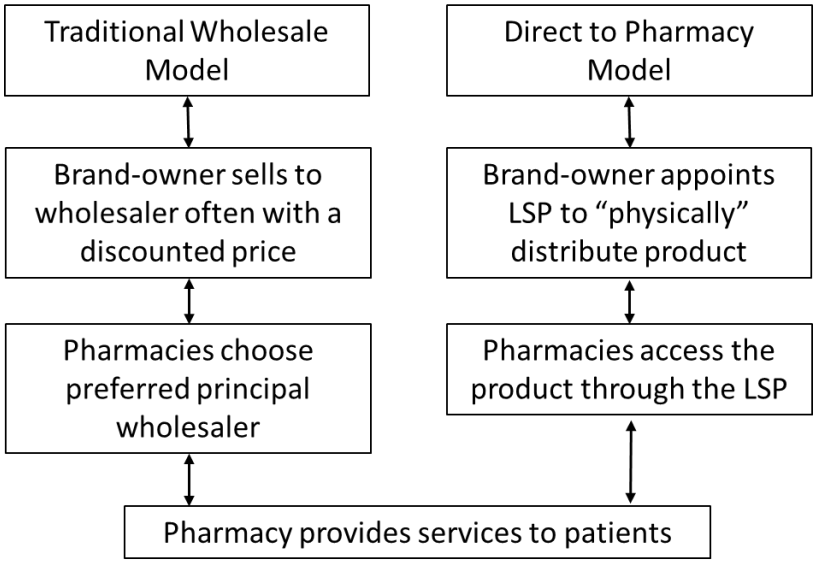
Pharmaceutical companies typically sell to wholesalers, hospitals and pharmacies. Most companies try and sell to all 3 channels in parallel to maximise revenue per drug and per market. They typically rely on the traditional IMS type data to fine-tune their pricing and promotional efforts in the hope of winning over customers from competition. Data is big business (source: 'IMS Health: Where The Best Medicine Is Data', Bloomberg Businessweek).

However, ask any pharma marketing executive on how happy they are with the commercial data they have on their customers and their ability to use this data pro-actively to make a real impact in how and what they sell and the answer will likely disappoint. The truth is that pharmaceutical companies still lack real-time and clear sales data on their products in relation to final customer buying behaviour. They lack visibility on patient buying choices and how this is influenced. Yet more and more of this valuable "big data" can be made available by designing a value chain model less dependent on "others" by selling more directly to pharmacies and hospitals. What is needed is more disruption started by companies such as Pfizer when they launched their "direct to pharmacy" program in various countries back in 2007 (source: 'AZ follows Pfizer into direct-to-pharmacy distribution', the Pharmaceutical Journal). Some other companies such as AstraZeneca and Amgen also introduced such a program (source: 'Pharma Takes Control Of Distribution Chains', Pharmtech.com).

# The Role of Wholesalers

Pharmaceutical companies are often not in control of patient buying choices as most of their selling still goes primarily via wholesalers. In turn, the wholesalers typically sell to the pharmacies. Wholesalers typically represent multiple brand owners and, in many cases, also represent competitors in the same single product category. The below

diagram illustrates the difference between the traditional and direct to pharmacy model.




Wholesalers have their own commercial objectives in promoting brand-owner products. This sounds like a contradiction, but it is not. They either sell re-actively and typically need to be prodded by the brand owners to promote their products or they 'play' with the product category and sell whichever product they can purchase (through discounting) at the best price. And more often than not they charge for the associated marketing activities to promote products and/or provide commercial (big) data. In other words, wholesalers charge a margin for their role in the commercial model.

Wholesalers use their own sales data to develop their own sales and marketing strategies. Based on a fee they will provide the brand owners with anonymised product data on the customers they sell to. They are also able to sell this same anonymised data to brand owner competitors in the same product segment or in fact to anyone else willing to pay for big data. One of the key questions is what value wholesalers provide the pharma companies themselves in terms of real commercial data at a time where market intelligence and big data drives businesses in many other industry sectors. There are many different views within the pharmaceutical industry on the role of wholesalers as part of the whole commercial model driving the industry.

It is interesting to see other industries in how they have dealt with similar pressures in recent years. In industry sectors such as electronics and fashion until about 10 years ago companies also sold in the way many pharmaceutical companies still sell today. Manufacturers and brand owners sold to wholesalers and distribution chains. They in

turn sold to the retailers who sold the goods to the consumers. What changed in these industries and what lessons can pharmaceutical companies learn?

## Online Retailing started more than 15 years ago

Its already more than fifteen years ago, that companies like Apple Computers and DELL computers started online retailing to gain more sales and marketing control over the products they sold. Interestingly, they retained the traditional retail channel through third parties however focussed their own sales efforts more and more on direct sales to consumers by creating online order platforms for customers. They didn't undercut the traditional third-party channel but created a direct sales channel online for a growing group of customers for their products. We all know the success story of single brand online sites such as the Apple Store and the revolution that was born fifteen years ago.

Very quickly, this revolution was followed by multi-branded online retailing sites such as amazon.com and many others. The interesting point about online retailing is ease of use and the ability to interact directly with end-customers and use sales data intelligently to customise services directly to individual customer needs. It is also an extremely good way to secure invoices get paid by securing pre-payment with credit cards. This also has a very positive cash flow impact. This last factor should not be underestimated as one of the key reasons' companies took to online selling in the first place.

Increasingly, online retailing is today used as a 'trading' platform across many industries between buying and selling parties apart from the pharmaceutical industry. In most of these industries we could not think of a business model without the online 'trading' platform being in place to facilitate buying and selling.

The good news is that there is some progress in the pharmaceutical industry. Companies like Pfizer, AstraZeneca have deployed early examples of selling direct to pharmacies in the UK and Australia. There are increasingly examples where industry partners within the pharmaceutical industry are creating online platforms to place orders and share information. In the US, Amazon in July 2018 acquired an online pharmacy company called Pillpack (source: 'Dispensing disruption: Are pharmacies ready for digital rivals?', The Sydney Morning Herald). As a reaction major US-based pharmacy groups such as CVS Health and Walgreens saw their share prices fall about 10 per cent. According to industry analysts, Amazon is eyeing a slice of the United

States' booming prescription drug market that in 2016 totalled $US328.6 billion ($443 billion).

In the UK some traditional wholesalers have started to offer LSP type models based on a 'cost for service'. In some countries such as Italy and Spain there are industry online trading sites emerging which can be used to channel orders from pharmacies and hospital customers directly to brand owners. However, these types of platforms are still not being used extensively by brand owners in selling medicines directly to hospitals and pharmacies. Logistics service providers are also starting to offer direct to pharmacy solutions in various regions around the world.

## Disruptive supply chain models are still largely missing in the pharmaceutical industry!

Commercial organisations within Pharmaceutical companies are still not sufficiently tuned into such developments and/or are extremely traditional to allow them to take advantage of such commercial online trading platforms and sell directly to pharmacy and hospital groups without the need to go via wholesalers. The direct to pharmacy model would allow pharmaceutical companies to increase margins as they sell directly. It would also provide direct access to the pharmacy market which is a step to getting better sales data on patients in markets.

On the commercial side there are changes happening within the pharmaceutical industries allowing companies to re-address their own channel management strategy and redefine how they interact with customers. Some companies have started small commercial "pilot' models to test the direct to pharmacy market.

This is an opportunity for companies to take more ownership of their business model and drive change to reduce operating costs and increase bottom line margins. Anno 2019, we see especially the "new comer" bio-pharma companies taking some advantage of these opportunities but less so the larger pharmaceutical companies.

In the area of hospital distribution, Government and healthcare regulators in the EU have developed public hospital tender programs to get better deals in terms of pricing but also in terms of product shelf-life and supply availability to decrease their risks of stock-outs and risks of obsolescence. Often the bio-manufacturers have not yet been able to increase their supply flexibility to adapt to these new commercial models

# Outsourcing
# Short- and Long-Term risks?

## 2. Cost Pressures on Manufacturing and Sub-Optimisation

One trend in recent years has been for pharmaceutical companies to reduce their manufacturing activities by outsourcing to third party manufacturers CMO's. In the short term this has allowed pharmaceutical companies to take fixed assets and personnel costs off their balance sheet and please investors. But has it also improved the value chain?

This trend has increased their ability to outsource drug manufacture to lower cost regions as well as apply single sourcing trends which we saw earlier in the automotive, electronics and fashion sector. This trend has seen pharmaceutical companies set up or continued to source from countries with tax incentives or subsidies in place to stimulate companies to set up production facilities there. It has also seen companies start to source manufactured drugs from countries such as China and India not always within the initially expected Quality and GMP (Good Manufacturing Practices) level. In the view of some companies, traditional risks related to supply of product, i.e. disruption risks impacting supply of product have diminished as they set up GDP (Good Distribution Practices) compliant supply processes with heir CMO partners. However, we have also seen some companies do an about turn on such a sourcing strategy, mainly related to GDP risks in the manufacturing and supply process

There is a longer-term risk to outsourcing which is linked to the ability to manage CMO's to ensure they provide cost effective production capacity and other services. CMO's seem to understand very well that once pharma companies outsource their production requirements and are linked into the FDA and EMA license approval as approved manufacturing sites, that they are limited to change to insourcing or to another vendor later. This has led to situations where CMO's play commercial hard ball to negotiate higher pricing on drug product manufacturing. This effect means that some pharmaceutical companies are 'squeezed' both on the commercial side (reduced market pricing for their products) as well as increased costs of production (CMO price increases) leaving them in a hard spot.

Another problem has been that of sub-optimisation within the production process in how production is set up between vendors and geographical locations. There is a real need for better integration of drug manufacturing to reduce the costs of supply within the upstream supply chain. Here too, due to outsourcing, pharmaceutical companies

are more dependent on their production partners to come up with more integrated production and packaging solutions. Integration relates on the one hand to upstream integration between API, primary drug manufacturing and secondary packaging sources. On the other hand, integration also relates to a greater ability to provide global integrated production networks instead of just regional ones. Postponement models can also play a role here.

Some CMO's are starting to see this opportunity to provide greater value to their clients by providing integrated production solutions regionally but also globally. However, as the industry sorts out the opportunity of upstream supply integration it is important to distinguish carefully both short term and long term what CMO vendors are really able to offer in this area. Some CMO vendors are offering to manage and co-ordinate the sourcing and the manufacturing of the upstream supply from raw materials to final pack. This can also help some companies who lack internal resource and/or expertise to manage their upstream supply chain. And although this type of proposition sounds attractive, most supply chain experts know how challenging it is to operate someone else's logistics, rates and timelines and take commercial responsibility for this as well as assume quality and legal liability.

Another traditional issue is the limitations CMO's have in storing finished product. Traditionally manufacturing sites still have the tendency to dictate supply terms related to batch production. Once product is produced CMO's want to ship out the product to vendor nominated warehouse site(s). This often creates a challenge for pharmaceutical companies in managing their S&OP replenishment model and often leads to companies carrying higher inventory of finished product than they would like to have.

The real cost opportunity of integration lies in integrating the drug product manufacturing and secondary packaging at one production site. This limits transportation costs between production sites, inventory carrying costs as well as reduced production lead-time cycles.

# The importance of Vendor Management

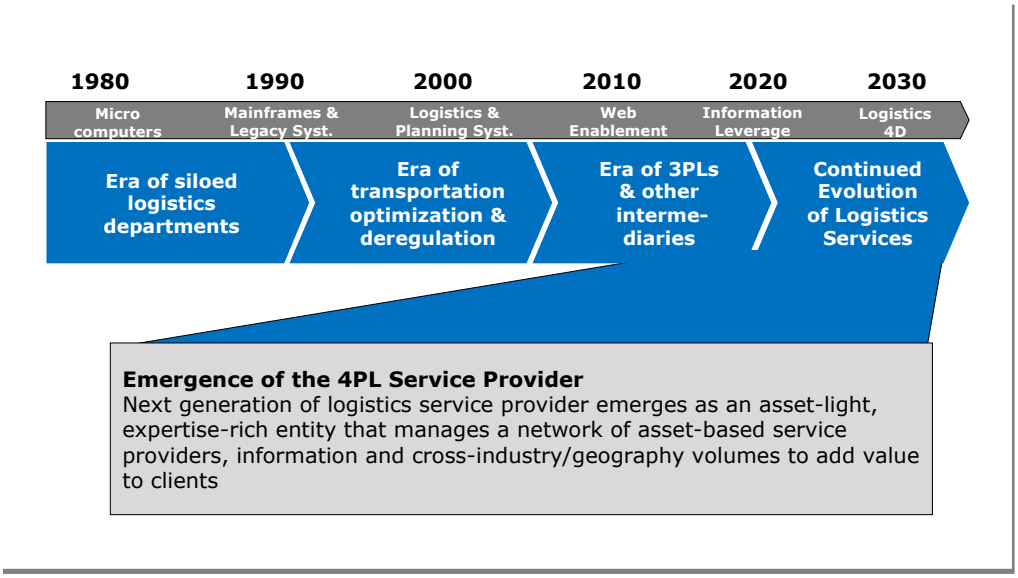
In other industries we already saw the rise of Vendor Management ten years ago as a profession to manage contracts with vendors. These are typically procurement experts who have excellent understanding of production processes, costs of production and the necessary commercial negotiating expertise to procure and manage supplier contracts.

We still see that many pharmaceutical companies could do with more Vendor Management expertise. Many companies don't have this expertise currently on board to enable them to effectively manage their CMO and logistics vendors in the area of API, drug production, secondary packaging processes and logistics. This results too often in one sided commercial contracts with production and logistics partners in which the terms and conditions are often in the favour of the vendor and hard to negotiate differently by the pharmaceutical company at a later point in time.

Effective procurement and vendor management requires professionals to understand production processes of their vendors, cost drivers and have a level of commercial negotiation skills to negotiate more balanced contracts. Too often, we see vendor management being conducted by research & development or operational people without the necessary expertise to manage vendors, run tenders and negotiate contracts.

One example in the logistics field is the strategic move some bio-pharmaceutical companies did in partnering with a 4PL logistics provider and thus harvesting meaningful points of margin due to this change.

The logistics landscape evolution:




The key attributes of the logistics service offerings:

**The Change in Key Attributes as 3PL Service Offerings Migrate**

| Relationship & Pricing Models | Service Offerings | Logistics Outsourcing Models | Key Attributes |
|---|---|---|---|
| • Partnership<br>• Value Based | Advanced Services | • Fourth Party Logistics Provider (4PL) | • Strategic relationship<br>• Broad supply chain expertise<br>• Knowledge & information-based<br>• Shared risk and reward<br>• Advanced technology capability<br>• Adaptive, flexible & collaborative |
| • Contractual<br>• Risk Sharing | Lead Logistics | • Lead Logistics Provider (LLP) | • Project management/contract management<br>• Single point of contact<br>• 3PL technology integration |
| • Contractual<br>• Fixed and Variable | Value-Added | • Third-Party Logistics Provider (3PL) | • Enhanced capabilities<br>• Broader service offerings |
| • Commodity<br>• Transaction | Basic Services | • Logistics Service Provider (LSP) | • Focused cost reduction<br>• Niche services |

The logistics service offering is evolving and thus adducing opportunities to rework transportation processes and related responsibilities. Since the cost component of transportation within the bio-pharmaceutical industry is substantial, there is a call to immediately initiate projects to tackle this space.

**"The cost of inventory is still considered as one of the last frontiers for pharmaceutical companies to really tackle. It seems we have at last arrived at this frontier, or have we?"**

### 3. High Inventory Levels and Safety Stocks

More than ever some pharmaceutical companies are shifting their efforts into improving inventory levels throughout their supply chain. This is an understandable development. In the past, companies tended to have a strategy in which having safety stock at every point in their supply chain was the norm. The reason was simple. Most companies had a fragmented supply chain. The manufacturing organisation dictated supply. The commercial organisation, often at affiliate level, dictated in-country stock requirements and both organisations were always right. The supply chain organisation was caught between a rock and a hard place and had little choice but to hold high safety stocks to allow for both requirements.

The topic of cost of inventory or inventory carrying costs (ICC) have often been ignored mainly for internal political reasons. However, in today's world, which company can ignore one of their key cost drivers? As internal organisations change and topics such as sales and operational planning (S&OP planning) become trendy words high on the corporate agenda it is important to understand what drives inventory and the costs associated to it.

Inventory is essentially all product in the supply chain which is not sold. Upstream, we talk about raw materials, API and drug product. Downstream we talk about finished goods ready to be sold. All this material typically sits in storage awaiting the next step in the supply chain process until it is sold… and paid for. Ask any Chief Financial Officer, inventory carrying costs play a large role in a company's cash flow.

Within the bio-pharmaceutical industry, high inventory level means shorter product shelf-life which has a direct impact on the commercial and sales activities with negative top-line results.

# Who is Actually Running the Supply Chain in Your Company?

## 4. Fragmented Supply Chain (internal ownership and information deficit)

Too often we still see that small to medium pharmaceutical companies don't have their supply chain functions centralised within one organisation. Operations and/or R&D departments run the upstream supply chain. The supply chain organisation runs the transportation pieces in the middle and some of the warehousing activities and the commercial affiliates each run their own in-country distribution.

There are many downsides to such a fragmented set up which results in sub-optimisation in terms of costs, opportunities to manage logistics service providers and using big data to provide visibility in key performance indicators across the whole supply chain. It also creates a "bottleneck" in driving strategic business and supply chain optimisation opportunities.

Supply Chain optimization can only be driven centrally having full responsibility over the end-to-end supply chain processes and integrating the Regulatory, Quality and Financial views together under one umbrella. Too often we have seen attempts to optimize only part of the supply chain creating supply issues before or after the re-worked segment and thus creating higher hick-ups such as stock-outs and missed sales.

**"Right now, we are facing a man-made disaster of global scale. Our greatest threat in thousands of years. Climate Change".**

David Attenborough recently at the United Nations Climate Change conference in Poland.

## 5. Corporate Responsibility – Greening of the Supply Chain

This is one topic which doesn't seem to be getting enough attention within most pharma companies. Its strange as there is so much political debate going on about CO2 emissions, sustainability in general and social responsibility and corporate leadership.

The good news is that many of the logistics service providers now have CO2 emission cuts within their own network high on their corporate agenda. However, the truth is that much still needs to be done and most pharmaceutical companies don't seem to be leading this agenda as part of their business and vendor management strategy.

We still see a lack of interest for pharmaceutical companies to collaborate within the industry. Low hanging fruit opportunities include the ability for logistics service providers operating multi-client warehouses to co-load pharmaceutical product from multi-clients on trucks for distribution across Europe. As a result, we still see today many trucks not loaded efficiently. We also still see a lot of (last minute) dedicated transport collection requests which often results in trucks being empty on the outbound or inbound leg. Better planning and more co-sharing can play a major role in a reduced carbon footprint as well as reduce transport related costs.

Cross collaboration in transportation management among the bio-pharmaceutical manufacturers would bring large savings in terms of CO2 emissions and also in terms of cost reduction. Despite several initiatives aimed at consolidating pharmaceutical freight, whatever the modal transportation is (road, air, sea), this saving paradigm remains largely untapped!

# Big Data – Where is it?

## 6. Big Data. Digitalisation of the Supply Chain

This trend has been ongoing for some time. The data has always been there, be it with the logistics service providers and/or with the wholesalers. Now more and more of this data is being shared with the pharmaceutical companies in the form of key performance indicators to help manage the vendor-client relationship. The question is how can we make what happens within the supply chain more transparent? Key supply chain processes like Demand Planning and Supply Planning are still very opaque and kept as such by the management. One way forward will be to change the role of the supply chain planners to become "super data analysts". Everyone agrees that this major evolution in utilising big data more intelligently is not easy to orchestrate internally. The companies who will be able to speed-up this transformation will be the winners.

Some pharmaceutical companies have already gone to the next level and started using this big data themselves to analyse their own supply chain in terms of volumes, transport lanes, mode of transport, costs of logistics services, costs of service, etc.

However, there are two key pre-requisites to being able to use big data intelligently.

The first aspect is knowing where to find and collect the data. Too often, we find that much of a company's supply chain related data is missing usually because companies do not have big data centralised in the first place. It means data needs to be found, often across a wide spectrum of logistics providers and/or internal organisations. Company ERP systems have often not been set up at the onset to manage logistics related data.

Second, being able to use big data intelligently is understanding the type of supply chain data that can be gathered from a logistics perspective and not only from a statistical or mathematical perspective. In our opinion, this is where the big challenge still lies within pharmaceutical companies in that they lack internal supply chain expertise to make sense of big data.

Traditionally, this is where consultants have played a role in using big data. However, it makes sense for pharmaceutical companies, especially the larger ones, to have their own centralised collection of big data and be able to run and model data for various purposes such as the ones mentioned above.

# Serialisation
# The Track and Trace Journey

## 7. Serialisation Requirements

For sure 2019 will be the year of serialisation in Europe. The EU Falsified Medicines Directive has set Feb 2019 as the live date for this legislation to be a mandatory requirement throughout the whole European Union.

In the United States, serialisation went into force already on Nov 26th, 2018 and is now being enforced by the US Food and Drug Administration (FDA) according the drug supply chain security act (DSCSA). However, there is a whole raft of measures each with its own timeline which pharmaceutical companies will need to understand to implement between now and 2023. It also remains unclear how the FDA will respond to non-compliance.

Meanwhile back in Europe, the EU Falsified Medicines Directive, officially named EU 2016/161, supplement to Directive 2001/83/EC, the Falsified Medicines Directive (FMD), dictates pharmaceutical companies to have an authentication process in place, based on serial numbers on individual pharma packages in place on all product sold within the European Union.

It will be up to each member state to set up its own national system, and to enforce the program within its borders on manufacturers and dispensers of drugs—with the result that there will be some variations from one country to another in how it's applied. However, the EU is trying to maintain a commonality with all of the Union, because "parallel trade" of products going from one EU country to another EU country is explicitly allowed for. (Iceland, Norway and Lichtenstein, members of the European Economic Area, as well as Switzerland, will participate in the FMD).

The European Medicines Verification Organisation (EMVO), set up last year by a consortium of most of the major European pharma trade associations, has said it "welcomes" publication of the regulation; it has already set up the European Hub for international data exchange in Belgium.

Key to the EU serialisation system is that it is a "book end" approach, with serialization at the front end with the manufacturer, and verification at the tail end, at the point of dispensing, and considerable discretion for what happens in between. This is in contrast

to the US system which by 2023 will ultimately track movement of individual pharma packages at each change of ownership. Under the FMD, intermediaries (such as wholesalers) are instructed to perform verifications on a risk basis, with certain drugs and certain transactions, but not as a matter of course. On the other hand, the directive requires the use of tamper-evident seals on packages—something which is lacking in US regulations (source: 'E.U. Serialization and U.S Serialization: Four Differences and One Big Similarity', LSPediA 2016).

To most pharmaceutical companies none of the above will come as a surprise. They have been working for many months together with their packaging and logistics partners to ensure the required serialisation printing processes and data requirements are in place. Typically setting up serialisation is an 18-month process. For this reason, there are some industry analysts who are concerned some pharmaceutical companies may not be ready come February 2019.

Gartner recently outlined in its report 'Supply Chain Reference Model for Track and Trace and Serialisation Across the Healthcare Value Chain' a whole list of big data opportunities related to having serialisation in place.

# BREXIT – Yes or No?

## 8. Brexit

This strategy paper would be incomplete without any mention of the Brexit process as one of the key challenges for supply chain leadership in 2019. At the time this report is written and published it is unclear what a Brexit will actually look like and more importantly what impact it will have on pharmaceutical companies distributing their medicines in the UK. That very fact is one of the key concerns to many companies as the deadline of March 29th, 2019 is fast approaching without a political deal between the UK and the EU.

Without getting caught up in the political process there are largely three scenarios which companies need to be aware of as part of their risk management process and contingency planning.

First, there is a deal between the UK and the EU based on the 'deal' already on the table and yet to be confirmed by the UK parliament (vote expected week Jan 14th, 2019). In a nutshell much will remain in the "transition" period as normal. There would be a period of time after 29th March 2019 until 31 December 2020 (or possibly later), to get everything in place and allow businesses and others to prepare for the moment when the new post-Brexit rules between the UK and the EU begin. It also allows more time for the details of the new relationship to be fully hammered out. Free movement will continue during the transition period, as the EU wanted. The UK will be able to strike its own trade deals - although they won't be able to come into force until 1 January 2021.

However, chances are high that this deal will not be rectified by the UK parliament come the week of Jan 14th, 2019. The two most likely remaining scenarios would mean either a 'hard' Brexit based on no deal or some type of vote that would defer or halt the UK retreat from the EU.

In the case of the second scenario, stopping Brexit would require a change in the law in the UK. The European Court of Justice ruled on 10 December 2018 that the UK could cancel the Article 50 Brexit process without the permission of the other 27 EU members and remain a member of the EU on its existing terms, provided the decision followed a "democratic process". In this case, it would remain business as usual for the immediate period.

However, according to many political analysts, the chance of a 'hard' Brexit seems to be increasing as each day passes towards the March deadline. In this case the UK would leave the EU on March 29th without any deal. It would exit the EU single market and customs union and take control of its borders and enforce its own UK laws again. In this scenario, the impact on cross border business between the UK and the EU is what companies should be most concerned with as it will impact business and supply chain operations in an immediate and big way.

For this reason and upon the UK's MHRA recommendation, many bio-pharmaceutical companies have already started to increase inventory levels in the UK to ensure they have enough product in place inside the UK to manage a period of time in which everyone will be scrambling to deal with border checks and customs processes. Apart from the uncertainty in how these new customs processes will operate it is already clear that government customs departments on both the UK and EU side are unprepared for a hard Brexit and that there is insufficient customs man-power in place to monitor and manage the new situation which will likely create a huge bottleneck and delays in moving product across the Channel into the UK for some time.

Longer term, supply chain experts have warned of the potential "bull-whip" effect of increased supply to facilitate the UK inventory ramp up. This could disrupt planning and inventory levels in the upstream supply chain with suppliers for much of 2019 (source: 'Could a Brexit bullwhip cause turmoil in European industrial production?'. Professor Jan Fransoo Nov 28th, 2018 on linkedin).

# Supply Chain Leadership

## 9. The Role of the Supply Chain Manager – more leadership is needed

We still see that in many pharmaceutical companies, especially the smaller ones, supply chain as a functionality is still not positioned strategically within the organisation. This is sad, as under supply chain management typically fall all the transportation and warehousing responsibilities and increasingly order management. Within this functionality typically all the lead-times to customers are managed as well as being the touch point with customers such as wholesalers, hospitals and/or pharmacies for order related queries.

Given the business challenges of pharmaceutical companies in today's business environment it only makes sense to ensure there is more supply chain leadership in place. More supply chain leadership is not just about adding a "title" to a position. It's about empowerment to make a difference. It requires a professional approach to supply chain management. Ensuring there is internal expertise, trained and empowered staff to work with internal stakeholders on a level playing field and to manage external vendor relationships with CMO's and logistics service providers. Understanding of big data in an intelligent way from a supply chain and a logistics perspective and not only from a mathematical perspective is crucial in making the right decisions about costs, service lead-times and vendor capabilities. Having professional supply chain leadership is a key requirement to read changes in the business environment and continuously optimise and fine-tune the company's value chain to suit.

The opportunity to differentiate from its competitors lies in supply chain management. This is where much needs to change in the next future. The best companies in terms of customer service levels at the lowest cost will be the ones with the most effective and flexible upstream and downstream supply chain and thus will bring outstanding top line and bottom line results.

**Europhia Consulting** is an international management consulting company specialized in the logistics and supply chain industry – notably in the life sciences sector. The company operates regional and global assignments for our clients.

**Supply Chain Operations SA**, based in Switzerland, is a specialized healthcare supply chain consultancy firm created in 2011 to serve the bio-pharmaceutical and medtech industry. We bring more than 120 years of end-to-end supply chain expertise to our valued customers.

Both companies work together on strategic assignments for clients globally. We do not pretend to have been able to capture all challenges and all insights and have deliberately focused this strategy paper on some of the key challenges we see based on our work with clients within the industry. For any questions or comments about this strategy paper please do not hesitate to reach out to us.

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