Trusted Experts in Serialisation Labeling and Artwork

We have received lots of great customer feedback about our newsletter to include some past articles and more industry news. Therefore, along with our current Be4ward posts, we have also included a Be4ward Executive Briefing, 'Top 10 Right-First-Time Tips to Streamline and Improve Your Artwork Process' compiled from previous posts. We have also selected some Top News Picks from the industry that we think are worth reading.

Click the links to go to the articles, or scroll down to find them below.

We hope you will find this Be4ward industry newsletter interesting and we would welcome any feedback.

Kind regards,

The team at Be4ward

Go to Featured Artwork Posts

Go to Featured Serialisation Posts

Go to Executive Briefing

Go to Top News Picks

Featured Artwork Posts

by Andrew Love

An Introduction To Packaging Complexity Management

Stock Keeping unit (SKU) and packaging component portfolio control is a critical activity for organisations. Ensuring the correct balance between a commercially advantageous portfolio, whilst minimising unnecessary pack and component variants is a challenge faced by many healthcare product companies as they grow their product range and expand into new markets. Therefore ensuring there are decision making processes in the organisation to manage required levels of complexity is a key aspect of effective pack management.

>> Read it offline

Read it online

8th Annual Pharmaceutical Packaging and Labelling Summit, 18 – 20 June, Crowne Plaza Zurich, Zurich, Switzerland

The 8th Annual Pharmaceutical Packaging and Labelling Summit, taking place on the **18th – 20th June 2018** in **Switzerland** will be addressing the key challenges surrounding:

- **Packaging**: Streamlining packaging processes to increase efficiency and embed flexibility
- **Labelling**: Implementing regulatory text requirements and ensuring effective information communication

- **Artwork**: Maximising space, reducing errors and optimising design to improve patient safety and compliance
- **Tamper-Evidence**: Enhancing anti-counterfeiting strategies and ensuring usability through best selection of tamper-evident features

>> Read it offline

Read it online

Have you developed your strategy to address the new EU Medical Device Regulation and In Vitro Diagnostic Regulation?

The new EU Medical Device Regulation and In Vitro Diagnostic Regulation are here and companies need to be deciding how they will address them. Approved by the European Parliament in May 2017, these new regulations are the biggest change to the legislative framework for medical device and in vitro diagnostic products in decades. As discussed in my previous blog on the subject, one aspect of this new legislation is the requirement to appoint a Person Responsible for Regulatory Compliance. This requirement has an impact on manufacturers and authorised representatives supplying medical device and in vitro diagnostic product in the EU market. Companies will need to implement many new or enhanced capabilities to meet these obligations.

>> Read it offline

Read it online

BSMA Europe Conference, 25 May, Rolex Center, Lausanne, Switzerland

Join Be4ward at BSMA's 3rd European Conference for the global life sciences supply chain community, taking place on May 25, 2018 in Lausanne, Switzerland

“Driving Digital Transformation of the Bio-pharma end-to-end Supply Chain”

The world’s leading community of Biopharma supply chain management professionals (Bio Supply Management Alliance – BSMA) will come together for the 3rd time in Europe on May 25th, 2018 in Lausanne, Switzerland.

>> Read it offline

Read it online

Join our Webinar, Do It Right The First Time: Reduce Compliance Risk and Streamline your Labeling and Artwork Processes into World-Class Capabilities

We all understand that packaging and artwork still present a significant compliance risk and delivering right-first-time artwork is a complex endeavor involving many moving parts. Furthermore, being right-first-time increases speed, reduces waste and raises confidence. Hear from a leading expert on how to increase patient safety, improve regulatory compliance and increase sales by providing error-free artwork and a streamlined Labeling process. Andrew Love will provide clear direction on how you can establish world-class labeling and artwork capabilities.

>> Read it offline

Read it online

Making Pharmaceuticals Exhibition and Conference, 24 – 25 April, Ricoh Arena, United Kingdom

Be4ward is proud to sponsor **Making Pharmaceuticals UK Exhibition and Conference** this year. The event will take place **April 24 – 25,2018, at Ricoh Arena, in Coventry, UK.** We hope to see you there.

>> Read it offline

Read it online

Featured Serialisation Posts

by Stephen McIndoe

Value Beyond Serialisation Compliance: Create a More Intelligent Supply Chain

In over 40 countries, regulatory mandates to secure the supply chain are already in place or in development. If you are currently on your serialisation journey, it's time to consider the value of your investment beyond compliance. In this blog I will share some of the immediate benefits that our clients have explored to; prevent counterfeiting in non-legislative markets, assist in product approvals, improve supply chain visibility, increase packaging operations effectiveness and enhance the patient experience, adherence and persistence – all as a result of leveraging their serialisation investment.

>> Read it offline

Read it online

---

10 Tips to Accelerate your EU FMD Serialisation Strategy: Part 1

The countdown is well under way, with significantly less than 18 months until the EU Falsified Medicines Directive (EU FMD) serialisation compliance deadline – will your company be ready in time? With 32 countries across Europe being affected by this legislation, in this blog series I will discuss 10 tips to consider whilst developing and implementing your EU FMD serialisation

strategy. Avoid supply interruption, make sure you have robust, realistic plans to address February 2019 EU FMD requirements.

>> Read it offline

Read it online

Executive Briefing

Top 10 Right-First-Time Tips to Streamline and Improve Your Artwork Prcocess

We all understand that packaging and artwork still present a significant compliance risk and delivering right-first-time artwork is a complex endeavour involving many moving parts. Furthermore, being right-first-time increases speed, reduces waste and raises confidence.

From this booklet, we can see that achieving high right-first-time is doable, but there are many parts to be addressed, requiring focus and persistence. As such, right-first-time is as much a mindset as an outcome.

We hope you find this information useful and helpful. We are always searching for

ways to improve our work, so of you have any feedback, please do not hesitate to contact us at enquiries@be4ward.com.

Tip 1 Measure your right-first-time — if you don't measure, you don't manage
Tip 2 Use codes to categorise errors, then ensure a thorough root cause analysis to eliminate source of errors
Tip 3 Make sure all of the input information is correct before starting
Tip 4 Ensure there is a comprehensive and effective end-to-end process with clear roles and responsibilities
Tip 5 Make sure the right quality of checks are undertaken by the right people
Tip 6 Ensure all people in the process have the appropriate skills, competencies and capabilities through effective training
Tip 7 Ensure there is effective cross-functional governance
Tip 8 There needs to be an appropriate and scalable suite of IT tools to support the process and people working with it
Tip 9 Ensure there is quality time and quality facilities to do quality work
Tip 10 You need to have the right culture, displayed across all teams involved in the end-to-end process to ensure success

Learn more and read the Executive Briefing

Top 3 News Picks

We share some of our latest news picks, on all topics related to Serialisation, Artwork, Proofreading, Packaging and Supply Chain Optimization. Here are three links from the many recently shared articles in the industry that we think are worth your time.

Manufacturing & Packaging

Press release

The Pharmaceutical Manufacturing & Packaging Awards 2018

GHP has announced the winners of Pharmaceutical Manufacturing & Packaging Awards 2018.

Year upon year medicine and health care organisations work with dedication and drive to ensure they are able to offer the best service possible to its needing patients. We often forget that behind the scenes companies and individuals are working hard to develop clean, safe and innovative products to encase some of the world's most vitally important items.

Click here to read the press release

EU Falsified Medicines Directive

Article

FMD plus Brexit equals potential supply chain disruption

The double whammy of the Falsified Medicines Directive and Brexit in quick succession risks a Europe-wide shortage of medicines, according to a European industry body.

Click here to read the article

Serialisation: DSCSA

Article

Six Months to DSCSA Enforcement Date

Saturday, May 26, the pharmaceutical industry will be just six months out from the DSCSA serialization enforcement date of Nov. 26, 2018. The deadline for compliance remained Nov. 27 of 2017, but last summer, the FDA stated they would not enforce the manufacturers' unit-level product identifier requirements under the DSCSA for another full year.

Click here to read the article

Featured Serialisation Posts

Value Beyond Serialisation Compliance: Create a More Intelligent Supply Chain

Leveraging serialisation investment to advance your supply chain and improve patient safety

In over 40 countries, regulatory mandates to secure the supply chain are already in place or in development. If you are currently on your serialisation journey, it's time to consider the value of your investment beyond compliance. In this blog I will share some of the immediate benefits that our clients have explored to; prevent counterfeiting in non-legislative markets, assist in product approvals, improve supply chain visibility, increase packaging operations effectiveness and enhance the patient experience, adherence and persistence – all as a result of leveraging their serialisation investment.

Prevent counterfeiting in non-legislative markets: Companies may have significant counterfeit risk in markets where serialisation is not mandated. Prior to having to implement serialisation capabilities for legislative reasons, it probably would not have been viable to invest for these currently non-regulated markets. However, the marginal cost of serialising additional products using existing capabilities is small, therefore may now be viable.

To further enhance the benefit of serialising such product, companies can also offer the downstream supply chain and patients the ability to authenticate product. This can be done through websites or smart device Apps, that are using services provided by a company's serialisation system. Typically, the incremental cost of such a service is relatively small.

Assisting in product approvals: Some of our clients have researched the use of serialisation track and trace in their supply chain to assist in product approvals. Some clients have recognised that being able to demonstrate to authorities tight control of a product once it is in their market, can better enable them to get that product approved locally. Like preventing

counterfeiting in non-legislative markets, this may include adding things like supply chain partner and patient apps to your serialisation capability to give those downstream partners information on the product and it's use.

Improving supply chain visibility: Companies can take the opportunity of using information already being gathered by their serialisation solutions to improve the visibility of stock and product movement within their supply chain. Companies can either use their serialisation systems to provide that visibility or tie that information stream into other business intelligence engines.

Improving packaging operations effectiveness: Serialisation technology can provide a detailed insight into the operation of individual packing lines. The information gathered can be used to assess and improve the effectiveness of both internal and external packaging operations. As with the previous examples, mining this vast amount of data for useful information can be done using existing serialisation systems, or by connecting the existing data feed to other BI tools.

Improving the patient experience, adherence and persistence: I often speak with clients who are looking for new ways to create a more valuable experience for their patients. Serialisation provides the unique identification of individual packs in a scannable form. If this unique information can be coupled with smart device Apps, it can help patients and/ or healthcare professionals ensure patients take the right medicine, at the right time for the course of a prescription.

Summary

We hope this information was helpful and that it has given you some idea about how to leverage the significant investment that you are already making in serialisation technology. If you would like to talk to us about our ideas and experience in this area, please don't hesitate to contact us.

Should you have any questions about this or any of my other blogs, or would simply like to request a copy of any of our serialisation booklets, please don't hesitate to contact me at Stephen.McIndoe@be4ward.com

Read it online

---

10 Tips to Accelerate your EU FMD Serialisation Strategy: Part 1

The countdown is well under way, with significantly less than 18 months until the EU Falsified Medicines Directive (EU FMD) serialisation compliance deadline – will your company be ready in time? With 32 countries across Europe being affected by this legislation, in this blog series I will discuss 10 tips to consider whilst developing and implementing your EU FMD serialisation strategy. Avoid supply interruption, make sure you have robust, realistic plans to address February 2019 EU FMD requirements.

The EU FMD legislation will require new capabilities to be implemented across many different functions of a typical company. The most obvious include:

- Regulatory and legislative management and government affairs who will have to understand new emerging requirements and represent the company in external influencing and governance bodies.
- Packaging operations, where serialisation will have to be applied to the product packaging at one or more lines.
- Distribution operations, where the more complex serialisation models, this operational impact will extend into these operations in central and/or local markets, where information on individual sale and shipment transactions needs to be gathered and added to the serialisation information.

- IT, particularly for the more complex track and trace models, where significant IT capabilities will be required to manage serial numbers and tracking information related to the product and its movement.

The serialisation strategy of a company and the resultant serialisation service that delivers and maintains the capabilities required, needs to ensure that the requirements of the EU FMD legislation are thoroughly understood and that appropriate capabilities are defined to meet those needs. These capabilities must then be implemented effectively in a timely manner to ensure product supply is maintained. Once serialisation capabilities become available, companies can then look to leverage them for product security and other benefits that are not directly driven by the EU FMD legislation. The following is a series of tips for developing and implementing your EU FMD serialisation strategy.

Tip 1: Identify and interpret the emerging and evolving EU FMD legislation

Serialisation legislation, particularly in its early iterations, tends to be somewhat vague, incomplete and sometimes contradictory. Interpreting the legislation and predicting its impacts can present significant challenges, requiring specific serialisation knowledge as well as new legislative relationships with local legislators.

The situation is no different in Europe as each of the National Authorities, National Medicines Verification Organisations and local supply chain stakeholders agree how each local model is going to work in detail.

Given the uncertainties in requirements and timing, organisations need to ensure there is a clear way of communicating their considered view of the legislative requirements at any particular moment. Failing to do this will potentially result in individual functions or groups creating their own interpretations, which at minimum is wasteful of resources, but at worst

results in capabilities being implemented which do not meet the eventual requirements of the legislation.

Tip 2: Understand the full impact of the EU FMD legislation on your company and product supply chain

Serialisation presents a potentially broad impact on a typical organisation. It is important to engage all of the potentially impacted parties early in the impact assessment phase to ensure that comprehensive solutions can be defined.

A further challenge is that multiple pieces of evolving legislation will often impact many of the same capabilities. Understanding these potential impacts and their likely evolution over time is key to ensuring effective solutions are defined and implemented in a timely manner.

Tip 3: Define solutions and implementation plans which strike the optimal balance between ensuring product supply and the caution that is prudent with the EU FMD legislation

There are often a number of supply chain configurations and technical options that can be brought to bear with particular serialisation legislative requirements. Short term tactical options have to be weighed against longer term strategic solutions. Some of the challenges that need to be addressed when defining optimal solutions include:

- Differing serialisation models being called for in differing pieces of legislation.
- Uncertainty in the detailed technical requirements as legislation evolves.
- Evolving and competing serialisation standards being developed by standards bodies and industry groups.
- The requirement for many supply chain nodes and assets to be able to handle multiple legislative requirements simultaneously.

- Deciding on the optimal degree of integration of serialisation capabilities with existing capabilities e.g. production control systems and ERP systems.
- Uncertainty in the timing of legislation.
- Striking the optimal balance between providing new equipment versus retrofitting existing equipment.
- Agreeing interfaces and implementation timelines with third parties.

Defining the timing of implementation plans, to a large extent, needs to be considered hand-in-hand with the solutions themselves. One risk that also needs to be considered is that of the ‘last minute rush’, or ‘Y2K effect’. By this I mean the risk that, as is so often the case with this type of legislation, everyone waits until the last minute to implement solutions, only to find that the supply base cannot cope with the peak in demand, driving up cost and forcing companies into non-compliance. This is a particular concern in the 2018 – 2019 timeframe as the USA, Europe and others all have legislation which becomes effective around this time.

It is crucial that your company has a comprehensive, robust and realistic plan in place to deliver EU FMD serialisation and avoid product supply issues. If you don’t have such a plan in place, act now – contact Be4ward to understand how we can help deliver your strategy and plan quickly, with minimal impact to your team. Should you have any questions about the EU FMD legislation, or would simply like to request a copy of any of our serialisation booklets, please don’t hesitate to contact me at Stephen.McIndoe@be4ward.com

Read it online

Featured Artwork Posts

[An Introduction To Packaging Complexity Management]

Stock Keeping unit (SKU) and packaging component portfolio control is a critical activity for organisations. Ensuring the correct balance between a commercially advantageous portfolio, whilst minimising unnecessary pack and component variants is a challenge faced by many healthcare product companies as they grow their product range and expand into new markets. Therefore ensuring there are decision making processes in the organisation to manage required levels of complexity is a key aspect of effective pack management.

In this blog series I will describe key features of a complexity management capability in an easy to digest format. I hope you find this information useful. We are always searching for ways to improve our work, so if you have any feedback, please do not hesitate to contact me at Andrew.Love@be4ward.com.

Why does Packaging Complexity occur?

Many healthcare product companies have broad product portfolios that they are selling in multiple markets. Beyond the US and big five European markets, sales volumes can drop dramatically for individual SKUs. Even within those markets, portfolio expansion and specialised products can result in low volumes. These effects result in an explosion of packaging components of ever decreasing volumes, creating a significant overhead cost (often referred to as a ‘hidden factory’) to manage and maintain, and reducing run times on packaging lines. We have seen healthcare product companies where >50% of their SKU portfolio have daily sales volumes of less than 30 packs, yet where packaging batches supply years of stock.

So why does this happen? We suggest four main root causes:

1. Maximising the sales value of the portfolio

As margins are squeezed and new blockbusters are becoming increasingly difficult to find, healthcare product companies are focusing their attention on maximising the value that they can extract from their current assets. One of the significant ways they can achieve this is to create and launch as many existing product variants, in as many markets, through as many channels as possible. For many companies this represents a significant change of strategy as traditionally they would have focussed their attention on a few large products in the larger volume markets.

2. The move to higher value, lower volume products

Many new products coming to market are for treating more complex conditions with increasingly tailored therapies. Whilst these products may be very high value, the product volume is typically much lower than traditional pharmaceutical products. Moreover they often have complex dosing regimes, devices or combination products that require specialist and complicated packaging.

3. Legislation and regulation drivers

Legislative and regulatory requirements are continually becoming more stringent, e.g. Braille, font size, authentication, tamper evidence etc. The requirements and development of this legislation is not harmonised across all of the different legislators globally, and in some cases it could appear that any effort to harmonise is met with a counter requirement for differentiation. This not only results in added complexity through new features having to be added to the packaging, but those requirements being necessary for some markets but not others (yet a product may be packed for all markets on the same packaging line).

4. Local requirements and preferences

Requirements here can fall into two groups – necessary requirements to meet the needs of the market e.g. language, and local marketing and

historical preferences e.g. a 28 or 30 tablet blister count. Some of these are captured in local regulation and it can be difficult to differentiate between what is a ‘must have’ and what is a ‘nice to have’. But even where it is not a mandated requirement, it can be very difficult to shift a local preference.

Packaging complexity creates a number of consequences for healthcare product companies and their customers. These include:

1. Compliance issues

It is essential that the correct products and components are supplied to the correct markets with the latest approved product information. With an ever-increasing portfolio complexity, exercising appropriate jurisdiction control over what is supplied where and when gets ever more difficult. Also, many companies have tried to overcome the complexity of supply to the smallest markets with standard ‘general export’ type packs, only to find unexpected and uncontrolled local repacking or over labelling activity e.g. where standard leaflets are replaced with locally sourced local language ones. These sorts of practices obviously present an unacceptable compliance risk if not managed effectively.

2. Lost commercial opportunities and product unavailability

Sometimes the financial trade-off between the supply of a unique variant to a specific market versus the cost of supply doesn’t merit selling that product in that location. Whilst that may be considered a victory in minimising complexity, it is a lost opportunity due to an unsuitable supply chain and there are patients in that country that don’t have that product or product-form available to them. It is therefore a bit of a hollow victory, and if the company had more cost effective capabilities to supply and maintain such variants, this could have been avoided.

3. Manufacturing inefficiencies

Small volumes obviously mean small pack runs and lots of change-overs. This is generally counter to the objectives of a packaging operation, whom are measured on cost of goods, production efficiencies and line utilisation.

We have seen many examples where the packaging line spends more time being changed over than actually producing product. Complexity can also create needs for specific additional tooling, equipment and hand finishing.

4. Support function inefficiencies

In addition to manufacturing inefficiencies, there is a whole ‘hidden factory’ in the support functions supporting the product and component range e.g. additional regulatory staff maintaining licenses and product information, increased volumes of artwork change, more purchasing activity, more warehouse space. This is often invisible and not considered in the cost of supply.

5. Obsolescence

There are two main types of obsolescence (where materials are no longer fit for use) that we would consider; packaging components and finished product. Economic order quantities can mean that the volumes of packaging components purchased have a disproportionate amount of forward cover versus the typical rate of change of those components. Therefore high amounts of materials can be written off when components are changed.

Similarly, high inventories of low sales volume finished pack stock, caused by minimum packaging line order quantities risks obsolescence due to shelf life expiry, causing either product write-off or repacking.

So why is packaging complexity necessary? We would suggest there are two main reasons:

- Market access: you cannot sell the product in this market without meeting these specific requirements, whether they be legislative or not.
- Commercial advantage: providing these features gives an advantageous position in the market and the incremental impact on cost of goods is outweighed by the commercial benefits obtained.

So some complexity may be considered ‘good complexity’ because it presents value in terms of the financial return from the sale of the product. The key is to learn how to cope efficiently with this ‘good complexity’ whilst developing methods to control the other type of complexity – the ‘bad complexity’.

Unfortunately there does not seem to be any ‘golden bullet’ that will help you to do this easily. Rather, there are a series of techniques that can be applied across the portfolio to manage the complexity and create an optimal portfolio. In the following pages we will outline a series of tips for how to do this. These are broken into two sections:

Part 1: Techniques to control non added-value complexity and,
Part 2: Techniques to cope with added-value complexity

Packaging Complexity Management Tip 1: Understand the product/therapy strategy and value of complexity

Is the commercialisation strategy for the product and therapy and the subsequent value of complexity understood?

Different products will have different requirements for the complexity of the packaging componentry and SKU portfolio. This can be driven from many factors, including but not limited to:

- Therapeutic, titration and dosing requirements
- Unmet medical needs
- Legislative requirements of countries the product will be marketed in
- Competitor activity and the competitive environment
- Commercialisation strategies for the product
- Market positioning and product cost profile
- Product lifecycle, line extension and patent expiry strategies
- Combination products, starter packs, special usage requirements and other opportunities to assist patients and healthcare providers
- Product protection, temperature and security requirements

- Likely local dispensing requirements

Prior to undertaking any complexity reduction activities it is important to understand and document these requirements to:

a) Ensure they are clearly defined and met

b) Ensure they are maintained as needed

c) Ensure appropriate control can be provided to prevent further non-essential requirements emerging

Packaging Complexity Management Tip 2: Understand the portfolio, volumes and lifecycle of SKUs

Is the portfolio, volumes and lifecycles of your SKUs understood?

The next step in a complexity reduction activity is a detailed understanding of the target SKU portfolio. The scope of this may be certain brands, geographic areas, supply chains or perhaps your entire company portfolio.

For the chosen portfolio, you will need to understand:

- The description of each SKU – product, dose form, strength, volume.
- Where are they supplied from, which market(s) are they supplied to, which distribution lanes are used?
- What is the subsequent component range?
- What are the SKU volumes?
- What is the financial contribution of each SKU?

In addition, it is important to understand where each SKU is on its product lifecycle; are volumes increasing or decreasing. Typically, products go through lifecycle: launch, growth, maturity, and tail off. The value of portfolio complexity often varies through this lifecycle. Therefore, it is important to understand where a product is on its lifecycle as products where the volumes are likely to increase need to be considered differently from tail products where the volumes are declining.

This is the first of a series of 7 blogs giving a view of methods to deal with packaging complexity. Should you have any questions about this or any of my other blogs, or would simply like to request a copy of my booklets, please don't hesitate to contact me directly on my email.

Read it online

8th Annual Pharmaceutical Packaging and Labelling Summit, 18 – 20 June, Crowne Plaza Zurich, Zurich, Switzerland

The 8th Annual Pharmaceutical Packaging and Labelling Summit is taking place on the **18th – 20th June 2018** in **Switzerland**. I will be chairing this event. Key challenges will be addressed, surrounding:

- **Packaging**: Streamlining packaging processes to increase efficiency and embed flexibility
- **Labelling**: Implementing regulatory text requirements and ensuring effective information communication
- **Artwork**: Maximising space, reducing errors and optimising design to improve patient safety and compliance
- **Tamper-Evidence**: Enhancing anti-counterfeiting strategies and ensuring usability through best selection of tamper-evident features

I will be presenting a mini-workshop at this event on, **How to Identify the Steps to Provide a Comprehensive Artwork, Labelling & Packaging Service**. This workshop will explore the impact of portfolio growth and complexity on artwork, packaging and labelling teams. I will be focusing on:

- What capabilities you might introduce to meet the challenges of growing product portfolios
- How to engage your organisation to make necessary enhancements compelling

- How to ensure you deliver successful outcomes

I will also be hosting an interactive round table discussion, **Global Regulatory Deep Dive – Identifying Similarities and Differences Across Key Market Requirements**. I will be focusing on:

For more information, follow the link to the event organizer website.

This event is will be attended by Be4ward.

Be4ward is a niche consultancy company helping Pharmaceutical, Biotech and Medical Devices companies and their supply base improve their serialisation, labelling and artwork capabilities. Be4ward help clients define the most efficient business processes, organisation design and, being completely independent, help them select and implement the most appropriate service providers and IT systems to meet their needs. Be4ward helps these companies improve patient safety and drive additional value from their product range. Corporate website: www.be4ward.com Contact: enquiries@be4ward.com

- Analyse the global regulatory landscape – how black market trade and product counterfeiting threatens the supply of pharmaceuticals across borders
- Ensure market compliance by identifying key international areas of regulatory similarity to exploit and differences to prepare for
- ISO 21296 – looking towards the new international standard on Tamper Verification techniques

Read it online

The new EU Medical Device Regulation and In Vitro Diagnostic Regulation are here and companies need to be deciding how they will address them. Approved by the European Parliament in May 2017, these new regulations are the biggest change to the legislative framework for medical device and in vitro diagnostic products in decades. As discussed in my previous blog on the subject, one aspect of this new legislation is the requirement to appoint a Person Responsible for Regulatory Compliance. This requirement has an impact on manufacturers and authorised representatives supplying medical device and in vitro diagnostic product in the EU market. Companies will need to implement many new or enhanced capabilities to meet these obligations.

For companies faced with these challenges, it begs the obvious question ‘So where do we start?’

Define your strategy

The logical first step is to define the company’s strategy for how to tackle the new regulations. Typically, strategy development would include:

1. Understanding of the current and new legislation.
2. Impact of the legislation on the company’s operations, including any opportunities that might present.
3. A gap analysis of each relevant aspect of the company’s operations against the requirements of the new legislation.
4. An assessment on existing and pipeline product registrations, testing and labelling.
5. Initial high level designs of potential new processes, capabilities and IT solutions.
6. High level roadmap for re-registrations, testing or re-labelling and implementing new processes, capabilities and IT solutions.
7. Cost and resource impact estimation.
8. Plan for the next phase of activity.

Some considerations when defining your strategy

From our experience of delivering large and complex legislative-driven

change, there are a number of things to think about when defining your strategy:

Take a cross functional approach: The impacts of the regulations are cross-functional so make sure that you have all relevant functions involved in defining your strategy. Avoid the temptation to 'slice and dice', allowing each function to independently develop their approach. The company needs a holistic response so develop your strategy as a true cross-functional activity. All stakeholder groups involved in the delivery of the legislation need to contribute effectively or the whole process is at risk of failure. Therefore, all parties must buy into their roles in the processes and actively contribute to them. This will rarely happen if they are simply passive bystanders in the design of the capabilities or the delivery of the resulting activities.

Define and agree some governing principles: Providing guidance to the team on what would be permissible or not, defining the 'rules of game' to all parties. This provides a boundary and decision-making framework for solutions being developed and should be approved and managed by the governance team.

Ensure effective cross-functional governance: Given the cross-functional and cross-organisational nature of the regulations, establishing the right inclusive leadership and governance is key to the long-term success of the activity. A cross-function governance team should therefore be established to steer the definition, establishment and ongoing delivery of your strategy. This governance body should include membership from all the stakeholder groups involved.

Build in flexibility: The implementation of solutions to address new legislative drivers is complex, not least because through the implementation journey, the legislation evolves. Unforeseen situations and challenges will arise, timelines may change, Delegated Acts may introduce further local requirements. Therefore, solutions defined need to have sufficient flexibility

to cope with further emerging requirements. This is not easy, but is a key challenge of which solution design teams must be made aware.

Look for standard approaches: In large and complex operations, it may be necessary to implement solutions at multiple locations. It can therefore be beneficial to develop standard approaches for solutions that can be replicated at each of these locations rather than ‘re-inventing the wheel’ at each one. This provides two benefits – it can be more efficient in preparing the solutions and learnings across the organisation can be shared. However, if taking this approach, local requirements must be highlighted and built into the developed solutions.

Put a capable, dynamic and motivated leader on the problem: These regulations are complex and evolving, touching many parts of an organisation. With the challenges facing the leadership that is charged with implementing such capabilities, they need to have a broad range of skills, the drive and motivation to anticipate risks and issues, as well as ensure they are effectively managed proactively. Furthermore, there will be many technical challenges to address so the leadership of the program needs to have the technical strength and breadth to succeed in managing these.

Involve local country teams and management early: Good change management practice encourages the involvement of those impacted early in the activity. The local country teams will be key in supporting implementation and ongoing operation of solutions implemented, as well as undertaking a significant role in product re-registration and labelling updates. Involving them early will ensure solutions are fit for purpose and that they buy into the activities you need them to do.

Refresh your strategy as appropriate: The implementation of the new regulations will take many years and requirements will probably evolve. The environment you operate in and your company will likely change in this time as well. Your strategy is therefore not a one-time activity. It needs to grow

and evolve as the surroundings change. Hence you need to build in regular reviews of the strategy to ensure it remains pertinent and comprehensive.

Your strategy will help you chart your course

As can be seen from the above, developing your strategy is a key point in your journey to address the issues presented by EU MDR/EU IVDR. It will help your company understand what needs to be done and how resources will be marshalled to address those challenges. The strategy processes need to be timely, giving enough time to undertake the strategy process itself effectively but also giving enough time to subsequently implement the new requirements, and it is an ongoing process tuning the company's response as situations change. Appropriate flexibility and risk mitigation needs to be built into your solutions and deployment plans. A good strategy will help facilitate a successful response to the legislation across your organisation.

If you are impacted by EU MDR / IVDR, start planning how to transition to the new requirements and avoid supply interruptions. Our Executive Briefing, An Introduction to the EU Medical Device Regulation (EU MDR) can help you understand the legislation and develop a strategy for transition.

Should you have any questions about this or any of my other blogs, or would simply like to request a copy of my booklets, please don't hesitate to contact me directly on my email.

Andrew.love@be4ward.com

Read it online

BSMA Europe Conference, 25 May, Rolex Center, Lausanne, Switzerland

Join Be4ward at BSMA's 3rd European Conference for the global life sciences supply chain community, taking place on May 25, 2018 in Lausanne, Switzerland

“Driving Digital Transformation of the Bio-pharma end-to-end Supply Chain”

The world’s leading community of Biopharma supply chain management professionals (Bio Supply Management Alliance – BSMA) will come together for the 3rd time in Europe on May 25th, 2018 in Lausanne, Switzerland.

Business leaders will address the strategic and tactical management of global sourcing, entry into the emerging markets, clinical operations management, information transfer from R&D to clinical trials to commercialization, manufacturing excellence, environmentally controlled distribution, supply chain risk mitigation, and supply chain management talent and career development, while ensuring compliance with expanding government regulations. The theme for 2018 will be: “Driving Digital Transformation of the Bio-pharma end-to-end Supply Chain”

Participate in this conference to:

- Find practical solutions and research delivered by 35+ speakers and panelists
- Network with 200+ executives from over 65 companies in BioPharma
- Join industry forums to discuss and solve your business problems
- Discover and leverage technologies and services from reputed suppliers
- Brand your enterprise in the biopharma industry

For more information, follow the link to the event organizer website.

This event will be attended by Be4ward. We hope to see you there.

The Bio Supply Management Alliance was born out of the need to create a worldwide community of operations and supply chain management leaders and professionals in the biotech, BioPharma, and biomedical device industries. It started in the San Francisco Bay Area, home to more than 600 life sciences firms; the Alliance provides a forum for collaboration, learning

and best practice sharing of practitioners, executives and thought leaders in these uniquely demanding industry sectors.

BSMA Europe has been launched in partnership with Biolog Europe, a life sciences supply chain association based in Belgium. Sharing values with the US BSMA alliance, BSMA Europe provides a global approach of Life Sciences supply chain organizations' challenges.

The mission of BSMA Europe is: to build effective and efficient supply chain strategy for the biotech, BioPharma, pharma and biomedical device industries by developing, advancing, and disseminating best practices, knowledge, and research. To encourage and promote supply chain innovation within the biotech, BioPharma, pharma and biomedical device industries for the highest quality and clinical outcomes in patient care and welfare. To create a supply chain community of thought and practice leaders from the business, professional association and academic sectors for information exchange, shared services, and collaboration.

Be4ward is a niche consultancy company helping Pharmaceutical, Biotech and Medical Devices companies and their supply base improve their serialisation, labelling and artwork capabilities. Be4ward help clients define the most efficient business processes, organization design and, being completely independent, help them select and implement the most appropriate service providers and IT systems to meet their needs. Be4ward helps these companies improve patient safety and drive additional value from their product range. Corporate website: www.be4ward.com Contact: enquiries@be4ward.com.

Read it online

Join our Webinar, Do It Right The First Time: Reduce Compliance Risk and Streamline your Labeling and Artwork Processes into World-Class Capabilities

We all understand that packaging and artwork still present a significant compliance risk and delivering right-first-time artwork is a complex endeavor involving many moving parts. Furthermore, being right-first-time increases speed, reduces waste and raises confidence. Hear from a leading expert on how to increase patient safety, improve regulatory compliance and increase sales by providing error-free artwork and a streamlined Labeling process. Andrew Love will provide clear direction on how you can establish world-class labeling and artwork capabilities.

PLUS: Register for this webinar and receive a complimentary copy of Andrew Love and Stephen McIndoe's latest book, **Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities**: Delivering patient safety, increased return and enhancing reputation – a must-have resource for business leaders looking to improve the performance of their company's labeling and artwork capabilities in the healthcare industry.

Register Today!

April 12, 2018 10AM PDT

REGISTER NOW!

Be4ward is a niche consultancy company helping Pharmaceutical, Biotech and Medical Devices companies and their supply base improve their serialisation, labelling and artwork capabilities. Be4ward help clients define the most efficient business processes, organization design and, being completely independent, help them select and implement the most appropriate service providers and IT systems to meet their needs. Be4ward helps these companies improve patient safety and drive additional value

from their product range. Corporate website: www.be4ward.com Contact: enquiries@be4ward.com

Read it online

Making Pharmaceuticals Exhibition and Conference, 24 – 25 April, Ricoh Arena, United Kingdom

Be4ward is proud to sponsor **Making Pharmaceuticals UK Exhibition and Conference** this year. The event will take place **April 24 – 25,2018, at Ricoh Arena, in Coventry, UK.** We hope to see you there.

The team at Be4ward will take the opportunity to present at the event. Neil Wetherall, Consultant, will be speaking on April 25, at 14:00 in Room A. Neil Wetherall will focus on the **EU Falsified Medicines Directive –An Update on the Latest Status and Key Learnings FromImplementation**. I will also be speaking on April 25, at 15:00 in Room A. I will focus on the **EU Medical Devices Regulations – An Update on Latest Status and Implications for Combination Products**.

This event is proudly sponsored by Be4ward and will be attended by Be4ward.

For more information, follow the link to the event organiser website.

Be4ward is a niche consultancy company helping Pharmaceutical, Biotech and Medical Devices companies and their supply base improve their serialisation, labelling and artwork capabilities. Be4ward help clients define the most efficient business processes, organisation design and, being completely independent, help them select and implement the most appropriate service providers and IT systems to meet their needs. Be4ward helps these companies improve patient safety and drive additional value

from their product range. Corporate website: www.be4ward.com Contact: enquiries@be4ward.com

Read it online

Share Forward to a friend

Send us an Email Be4ward Website

Our mailing address is:
Be4ward
48 Warwick Street
London, W1B 5AW
United Kingdom

Add us to your address book