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, '10 Tips to Accelerate your EU Falsified Medicines Directive (FMD) Strategy' 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

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Go to Featured Serialisation Posts

Go to Executive Briefing

Go to Top News Picks

Featured Artwork Posts

by Andrew Love

Are you a Medical Device Manufacturer or an Authorised Representative supplying product in the EU market? Do you understand your obligation to appoint a Person Responsible for Regulatory Compliance under the new EU MDR and IVDR legislation?

Billed as the most significant change to the medical device legislation in decades, the Medical Devices Regulation (MDR) – Regulation (EU) 2017/745 – and In Vitro Diagnostic Medical Devices Regulation (IVDR) – Regulation (EU) 2017/746 seek to increase the safety and effectiveness of medical devices available in the EU market. 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.

>> Read it offline

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Making Pharmaceuticals Europe Exhibition and Conference, 13 – 14 March, Brussels

Be4ward is proud to sponsor **Making Pharmaceuticals Europe Exhibition and Conference** this year. The event will take place March 13-14, 2018, at Brussels Expo, in Brussels, Belgium. This event will be attended by Be4ward and I will be taking the opportunity to present. We hope to see you there.

>> Read it offline

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Watch our On-Demand Webinar on EU MDR Labeling Compliance: Learn the Lessons from UDI

EU MDR is being viewed as an extension of the FDA's UDI (Unique Device Identification), but also a 'step up'. However, it's more detailed and more complex due to the local language requirements needed for Europe.

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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

Watch our On-Demand Webinar on EU Falsified Medicines Directive: How to Develop a Comprehensive Plan with Rapid Implementation

Getting ready for Falsified Medicines Directive (FMD) compliance can be a complex process. Avoid supply interruption. Make sure you have a robust, realistic plan to meet the February 9, 2019 EU FMD compliance deadline.

Less than two years remain — will you be ready in time? With 32 countries across Europe being affected by this serialisation legislation, the entire industry must prepare. This webinar will help ensure you have a solid, comprehensive strategy and implementation plan in place before it is too late.

>> Read it offline

Read it online

10 Tips to Accelerate your EU Falsified Medicines Directive (FMD) Strategy

The countdown is well under way, with significantly less than two years 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 booklet we 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.

Key learning 1 Identify and interpret the emerging and evolving EU FMD legislation
Key learning 2 Understand the full impact of the EU FMD legislation on your company and product supply chain
Key learning 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
Key learning 4 Understand the immature and evolving solution supply base and select appropriate implementation partners for EU FMD
Key learning 5 Resource implementation projects with sufficient serialisation specific knowledge to minimise the risk of wasted resources, delays and implementation failure of EU FMD
Key learning 6 Compare your global and local requirements for EU FMD
Key learning 7 The need for flexibility beyond EU FMD implementation
Key learning 8 Define and agree some governing principles for EU FMD
Key learning 9 Implement effective cross-functional governance for EU FMD
Key learning 10 Understand how to start planning your EU FMD serialisation strategy

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.

EU Medical Devices Regulation

Article

Crucial changes from new medical device regulations

Andrew love explores how the ‘most significant changes to medical device legislation in decades’ will impact their supply and implementation.

Click here to read the article

Value Beyond Serialisation Compliance

Article

Making Use of Serialization Data

An information expert from Merck shares advice on how data can be used, challenges to overcome, and what may be in store in the future. Like any pharmaceutical manufacturer, Merck & Co., Inc.'s serialization approach is driven by the Drug Supply Chain Security Act (DSCSA) in the US, Falsified Medicines Directive (FMD) in the European Union, and similar country-specific regulations around the globe. But the company is also deriving value from serialization data, and sees potential uses for the data further in the future.

Click here to read Part 1

Click here to read Part 2

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

Watch our On-Demand Webinar on EU Falsified Medicines Directive: How to Develop a Comprehensive Plan with Rapid Implementation

The countdown to EU FMD compliance is underway. Join us and be prepared.

Getting ready for Falsified Medicines Directive (FMD) compliance can be a complex process. Avoid supply interruption. Make sure you have a robust, realistic plan to meet the February 9, 2019 EU FMD compliance deadline.

Less than two years remain — will you be ready in time? With 32 countries across Europe being affected by this serialisation legislation, the entire industry must prepare. This webinar will help ensure you have a solid, comprehensive strategy and implementation plan in place before it is too late.

Without an effective plan, you risk facing significant product supply issues once the deadline is enforced. Join Be4ward, OPTEL and Verify Brand for this informative webinar –

Learn how to:

- Develop an effective strategy for EU FMD compliance with low risk to your business
- Implement your EU FMD plan with minimal impact to your resources
- Identify key solutions, specially designed for rapid implementation

Speakers

Speaker Name: Jean-Pierre Allard

Title: Chief Technology Officer

Organization: OPTEL GROUP

Speaker Name: Stephen McIndoe

Title: Serialisation Practice VP

Organization: Be4ward

Since 1999, Stephen has helped many pharma and biotech companies and their supply chain partners to define and implement end-to-end serialisation capabilities to both meet legislative requirements and deliver other business benefits. Stephen heads the serialisation practice at Be4ward, managing a group of specialists offering independent advice through a combination of deep subject matter expertise and excellent consulting skills.

Speaker Name: Dhermita Desai Mulchandani

Title: Senior Project Manager, UK and EU

Organization: VerifyBrand

Dhermita Desai's operational skills have been honed through 16 years of work in the Life Sciences industry, where she has authored validation documents and has helped onboard more than 100 trading partner CPOs and CMOs. As a senior project manager at Verify Brand, Dhermita leverages her knowledge of EU FMD serialization and the critical role CMOs and CPOs play in the interoperability of pharmaceutical value chains to ensure that her clients' serialization projects meet regulatory market and business requirements. Dhermita's previous experience includes quality and program management roles at Amdipharm Mercury Company, Mercury Pharma, Lexon UK and Reckitt Benckiser Healthcare International. She views constantly evolving regulatory compliance mandates as tremendous opportunities to leverage her organizational and management skills to ensure that her clients' serialization projects meet regulatory market and

business requirements. Dhermita has a degree from De Montfort University in Pharmaceutical Chemistry.

Watch on-demand now!

WATCH NOW

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 for more information.

Read it online

Featured Artwork Posts

Are you a Medical Device Manufacturer or an Authorised Representative supplying product in the EU market? Do you understand your obligation to appoint a Person Responsible for Regulatory Compliance under the new EU MDR and IVDR legislation?

Billed as the most significant change to the medical device legislation in decades, the Medical Devices Regulation (MDR) – Regulation (EU)

2017/745 – and In Vitro Diagnostic Medical Devices Regulation (IVDR) – Regulation (EU) 2017/746 seek to increase the safety and effectiveness of medical devices available in the EU market. 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.

Who will be required to appoint a Person Responsible for Regulatory Compliance?

The regulations require that manufacturers and authorised representatives have permanently, and at their disposal, at least one person responsible for regulatory compliance. This isn't necessarily an employee, but a service that is provided by a person that must be accessible to the organisation. The person is responsible for ensuring the conformity of devices are checked prior to release, including that technical documents and certificates of conformity are accurate.

What are the obligations for organisations not established in the Union?

Regardless of your location around the world, if your organisation is supplying medical device and/ or in vitro diagnostic product in the EU market, you will be required to appoint a Person Responsible for Regulatory Compliance.

What are the qualifications of a Person Responsible for Regulatory Compliance?

Accepted qualifications for a Person Responsible for Regulatory Compliance are either of the following:

'(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy,

engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.'[1]

What are the responsibilities of a Person Responsible for Regulatory Compliance?

A Person Responsible for Regulatory Compliance is responsible for ensuring that:

'(a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;

(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;

(c) the post-market surveillance obligations are complied with in accordance with Article 10(10);

(d) the reporting obligations referred to in Articles 87 to 91 are fulfilled;

(e) in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued.'[2]

What do I need to do from here?

Companies should incorporate the potential requirement to appoint a Person Responsible for Regulatory Compliance in their compliance plans. To understand if your organisation is impacted, a review of the general obligation statements in relevant articles should be performed.

For companies obligated to appoint a Person Responsible for Regulatory Compliance, you should identify an individual that meets the qualifications. There's a possibility that larger companies have already got the capabilities

to meet this role. However, the likelihood is that many smaller companies will have to search outside their organisation to find a Person Responsible for Regulatory Compliance.

Once a Person Responsible for Regulatory Compliance has been identified, companies will need to focus on how they will introduce this new responsibility within their organisation. Companies should consider updating the relevant processes to transition to this new way of working. Overall, this will better enable companies to meet the timelines of the legislation and the re-registration of their products by May 2020 and May 2022.

Summary

As can be seen from the above, it is essential to ensure that you meet the general obligations for a Person Responsible for Regulatory Compliance in the new regulations. An assessment and action plan will help ensure a successful outcome for 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.

I hope you found this information useful and helpful. 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

Making Pharmaceuticals Europe Exhibition and Conference, 13 – 14 March, Brussels

Be4ward is proud to sponsor **Making Pharmaceuticals Europe Exhibition and Conference** this year. The event will take place March 13-14, 2018, at Brussels Expo, in Brussels, Belgium. This event will be attended by Be4ward and I will be taking the opportunity to present. We hope to see you there.

The team at Be4ward will take the opportunity to present at the event. Andy Cumming, Consultant, will be speaking on March 13, at 11:30 in Room B. Andy Cumming will focus on the **EU Falsified Medicines Directive –An Update on the Latest Status and Key Learnings From Implementation**. I will also be speaking on March 13, at 12:10 in Room B. I will focus on the **EU Medical Devices Regulations – An Update on Latest Status and Implications for Combination Products**.

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, 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

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downloadable resources on the latest EU MDR, IVDR and Emerging Market Regulation updates

EU MDR Labeling Compliance: Learn the Lessons from UDI

EU MDR is being viewed as an extension of the FDA's UDI (Unique Device Identification), but also a 'step up'. However, it's more detailed and more complex due to the local language requirements needed for Europe.

The introduction of UDI requirements into the EU is good news for organizations that are already along the pathway of adopting systems and processes to support FDA UDI compliance. However, for those that aren't – and indeed those that may have made only basic adjustments to their labeling infrastructure in response to the regulations – there are five key learnings that have emerged from the UDI experience that may help inform best practice adoption with EU MDR.

Join us for this 60-minute information packed webinar to discover why EU MDR will change the medical device labeling landscape globally and how to best meet the impending challenges.

Key Learning Objectives:

- Understand what EU MDR compliance means for your business and how it will affect your labeling processes
- Develop an understanding of the market's perceptions of EU MDR
- Recognize what the biggest labeling compliance challenges ahead are and how to proactively overcome them
- Embrace the lessons from UDI to work smarter in meeting the implementation deadlines of MDR by May 2020 and IVDR by May 2022

- Learn about a labeling system that can adapt to regulations that will be following for other countries that are not part of the US or EU, so that any new regulation does not have a similar size impact

Speakers

Andrew Love
VP Capability Development
Be4ward

Andrew Love is a multi-award-winning packaging and artwork management strategist, leader and author. Andrew spent 10 years as head of global packaging design operations at GlaxoSmithKline, the world's second largest pharmaceutical company at the time. During his time there he oversaw the transformation of the global artwork management activities into a world-class, award-winning capability. Andrew is one of the founders of Be4ward which helps pharmaceutical, biotech and other healthcare companies and their supply base to improve patient safety and drive additional value from their product range. He now develops products for, and works with, a number of pharmaceutical and healthcare companies in achieving these aims. Andrew, a professional engineer and MBA with over 20 years of experience, has worked with many of the world's largest life-sciences companies.

Mark Cusworth

VP Research and Development
PRISYM ID

Mark Cusworth has over 15 years of experience heading up a team providing off the shelf and tailored solutions to Life Science companies. During this time, he has seen many changes to the industry including significant tightening of regulations and challenges of globalization. His primary objectives are to target the ongoing investment in research, development and quality effectively and to lead the company in-house research and development to maintain the market leading position of PRISYM ID's world class label management software.

Watch on-demand now!

WATCH NOW

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Andrew.love@be4ward.com

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