Trusted Healthcare Experts
Transforming Supply Chains

Welcome to our Be4ward newsletter, our opportunity to share with you our most recent articles, along with our company and wider industry news.

In this issue we share our company news, including the next of our summer webinar watch-backs, and the launch of a new report written by our Principal Consultant Grant Courtney and commissioned and published by EFPIA.

As always, we share our consultant's thoughts and knowledge via a series of blogs, concluding our look at **Excellent Packaging Artwork Capabilities** and in our **Ensuring Effective Translations** series we look at translation specifications and briefing your translation provider. You can find these in our Featured Blog Post section below, available for you to read on or off-line.

We're pleased to share with you our Executive Briefing for this issue: **Responding to Pharmaceutical Serialisation and Product Coding Legislation** outlining the requirements of serialisation and related product coding legislation, discussing what needs to be done to address it and identifying some next steps to effectively manage the risk.

In our Top News Picks we share with you a few articles from the industry that we think are worth a read.

We appreciate you taking the time to enjoy sharing our news and updates. As always we welcome your thoughts and comment. If you and your business require advice or assistance in any of these areas, please do not hesitate to get in touch.

Kind regards,

The team at Be4ward

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Be4ward Company News

Be4ward and EFPIA publish report highlighting the benefits of FMD in the hospital setting

Be4ward Principal Consultant Grant Courtney has researched and written a new report published by EFPIA (The European Federation of Pharmaceutical

Industries and Associations), which looks beyond the prevention of falsified medicines to understand what other benefits can be gained in the hospital setting.

The EU FMD, introduced to prevent fake medicines, has also brought about the standardisation of medicinal product identification and common 2D barcodes on all prescription medicinal packs. This enables hospitals to leverage further benefits opportunities which were difficult to achieve before this level of harmonisation and barcoding prevalence.

The report, commissioned by EFPIA, illustrates how benefits exist at all points across the hospital supply, where the EU FMD pack is handled, stored and processed including in: Logistics, Manufacture & transformation and Clinical.

The use of barcoding and product identification brings impressive financial benefits to those hospitals which leverage them. In one hospital alone they were able to save £4 million through the reduction of over ordering products. These savings can be used to offset the costs of implementing and operating the EU FMD within the hospital setting.

Applications of a standardised 2D barcode go beyond supply chain efficiencies and increasing patient safety, having impacts on clinical effectiveness and new payment models. These barcodes even open up the opportunity to digitally web enable products allowing the provision of live data and services directly to the healthcare provider.

Read Report Here

Read Grant's EFPIA guest blog post

Be4ward Published

PATIENT SAFETY

Falsified medicines and the hospital setting

The EU Falsified Medicines Directive (EU FMD) introduced new requirements for hospitals to verify the authenticity of prescription medicines. A year on and hospitals are working to reduce the cost impacts and starting to leverage significant additional benefits. A new report published by Be4ward, the supply chain transformation consultancy, looks beyond the prevention of falsified medicines to understand what other benefits can be gained in the hospital setting.

Why the EU FMD was introduced

Fake medicines are often perceived to be an issue primarily affecting developing countries. While this is true, it is easy to overlook the very real threat that Europe is facing from falsified products. We only need to consider what has occurred over the past six months during the COVID outbreak and we see an influx of fake PPE and medicines onto the market. Between 2013-2017 there were 400 incidents of falsification reported in the EU and, following an Interpol operation in 2017, nearly €7 million medicines were seized at the EU border.

This is not just an issue related to internet sales of medicines or supply to retail community pharmacies. Falsified products have found their way onto the shelves of European hospitals. Between 2001-2014 more than 10,000 packs of medicines stolen from Italian hospitals by criminal gangs found their way back into the legitimate supply chain. These packs had been removed from the control of supply chain and therefore their condition could not be guaranteed, they were therefore considered falsified. The products involved included treatments for epilepsy, prostate cancer and schizophrenia.

Falsified medicines could be fatal or cause irreversible harm to a patient; they also contribute to antimicrobial resistance.

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Dealing with the impacts caused by fake medicines puts a cost burden on health systems in addition to the economic and societal impacts.

Faced with this very real and increasing threat, the European Commission acted and introduced the EU Falsified Medicines Directive (EU FMD) (2011/62/EU). The scope impacts almost all prescription medicines with a Marketing Authorisation and came into force in February 2019.

How the EU FMD impacts hospitals

The EU FMD introduced two harmonised measures to help ensure medicines within the European Union are safe and free from these medicines is properly authorised. The concept is relatively simple – every individual pack now includes two safety features: the first is a 2D barcode (DataMatrix) that holds a unique identifier (UI). This barcode must be scanned by the hospital and the UI checked in a national repository to verify it is authentic and the product can be dispensed.

In addition to verifying the authenticity of the UI, the recall status and shelf life of the product is also checked automatically, preventing issues due to out of date products being used. The second safety feature is a tamper evident device e.g. a label, which ensures the contents of the pack have not been altered or accessed. Although the barcode checks ensure 100% repository systems are designed to provide almost immediate verification responses, there is still an impact on the logistical operations of hospitals.

Over 100,000 pharmacies have connected to the system across the EU and retail community pharmacies typically integrate the UI verification process into their workflows, usually at the point the medicine is picked and dispensed. The hospital environment is significantly different to the retail setting due to factors such as the volume and variety of medicines received, and the fact that the majority of products are administered to a patient. Workflows that work in retail pharmacies are not appropriate in the hospital setting and hospitals have had to set up specific processes to verify the UIs, usually as part of the incoming goods operations. With hundreds and thousands of packs being received every single day, these processes can consume additional resources and it is not unusual for between one and four people to be required to carry out these tasks, depending on the volumes involved.

How hospitals are responding

Faced with an increase in staff to verify medicines, some hospitals have started to address the challenge. The use of robotics and conveyor systems are helping to reduce the manual labour involved. Combining the verification step with other activities which require the packs to be manually handled is also reducing duplication of effort.

Hospitals that participated in research experience around 80% of medicinal packs could be processed using automated means and were working towards establishing that capability. This could significantly reduce the additional headcount required to make verification more efficient.

Moving beyond detection of fake products

The EU FMD has brought about the standardisation of medicinal product identification and common 2D barcodes on all prescription medicines. This enables hospitals to leverage further benefits and opportunities which were difficult to realise before this level of harmonisation and barcoding prevalence.

One of the features of the new 2D DataMatrix barcode is that, in addition to the UI, it also contains the product code, batch/lot number and expiry date. The ability to scan the data using the 2D DataMatrix, capture it in systems and then utilise this, opens up many opportunities for hospitals for example:

- Error reduction during data capture and pack handling.
- Closer integration with receiving processes.
- More use of automation eg: picking and robotics.
- Access to digital data and services leveraging the barcode.
- Increased transparency through product identification and data.

Benefit types and where they occur

The report's research data from a broad range of primary and secondary sources in order to identify benefits. These benefits were grouped into three basic categories: (1) Improved Patient Safety, (2) Operational Efficiencies and (3) Enhanced Clinical Effectiveness. These are not mutually exclusive, and many initiatives showed results across several of these different types.

By following the flow of medicines through the supply chain it was clear that benefits also occur across the end to end product flow, from goods in through to administration to the patient. Various functions within a hospital are able to make use of the 2D DataMatrix.

The logistics and procurement functions are better able to manage the order to cash processes including purchasing of medicines, receiving, inventory management and demand planning. Many hospitals ▶

The Be4ward / EFPIA report as featured in this month's Clinical Services Journal. Read the full article here.

REGULATORY AFFAIRS

FMD alerts in 2020: where we are a year into legislation

It's been more than a year since EU FMD came into force in February 2019 and, after initial problems bedding in the new systems, false alerts remain a problem, preventing the realisation of the full benefits of the directive

With many grace periods now coming to an end, where are manufacturers on the EU FMD journey and what are the real consequences of unresolved alerts moving forward? Grant Courtney of Be4ward examines the reasons behind these alerts occurring and looks at the action stakeholders must now take to keep the supply chain flowing.

On 9 February 2019, new legislation was introduced in the EU with the aim of increasing patient safety by preventing falsified products from entering the pharmaceutical supply chain. The EU Falsified Medicines Directive (2011/62/EU), or EU FMD as it is known, called for a significant overhaul of the existing pharma supply chain system, requiring the establishment and implementation of new organisations and systems needed to authenticate every medicine distributed throughout the European market.

Initially, most of the stakeholder effort was focused on meeting the compliance deadline. For manufacturers, this included upgrading production lines, putting in new IT systems, establishing new processes and running regulatory pack change programmes. Products were generally ready in time across the industry and from 9 February 2019, as per the directive, all packs that were released onto the market carried a 2D data matrix barcode with a unique identifier (serial number), along with a tamper evident feature to ensure the integrity of the pack. It would be wrong to believe that hitting the compliance deadline was the end of the journey. In many respects, February 2019 was just the starting point for the EU FMD.

More than 100 million prescribed packs are now scanned every single week. The scale of the systems is impressive and the EU FMD has fundamentally changed the way in which prescription medicines are manufactured and how they are managed prior to dispensing. These changes present an even greater challenge than the technical ones already encountered, and the implications and impacts are only just starting to surface a year after the deadline.

For most of the millions of packs being dispensed each day, pharmacists receive positive confirmation that the unique identifier is valid and may allow the pack to be dispensed. When this occurs, everything runs smoothly; however, not all scans end with a positive confirmation.

Bugs in the machine

The EU FMD systems are designed to identify any unique identifier on a pack that is not in the system or has a status that means it should not be dispensed. When a pack fails to authenticate, the system generates an alert that is distributed to several stakeholders, including the Market Authorisation Holder (MAH).

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Grant Courtney's article *FMD Alerts in 2020 – where we are a year into legislation* featured in the September issue of Manufacturing Chemist – Read the full article here.

Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities - Andrew Love

Making Pharmaceutical Packaging that is Easy for Elderly People to Open – Stephen Wilkins

View On Demand

* please note, as this is a watch-back the interactive chat and Q&A function is not available

Company Blog Posts

EXCELLENT PACKAGING ARTWORK CAPABILITIES PART 5 – LEADERSHIP, GOVERNANCE AND TECHNOLOGY

By Stephen McIndoe- VP of Be4ward

In part 4 of my blog series on how to create excellent packaging artwork capabilities, I looked at the third of our defined processes, Supporting Processes and the influencing aspects of organisation design. Here in the final part five I will look at our final two capabilities: the importance of establishing the right inclusive leadership and governance and the role technology plays in establishing artwork capabilities.

>> Read it offline

Read it online

ENSURING EFFECTIVE TRANSLATIONS – TRANSLATION SPECIFICATIONS

By Andrew Love - VP of Be4ward

As we hit the halfway mark in this series of blogs covering the basics on Ensuring Effective Translations, the next set of tips guide you through establishing a set of standards for working with your translation provider.

>> Read it offline

Read it online

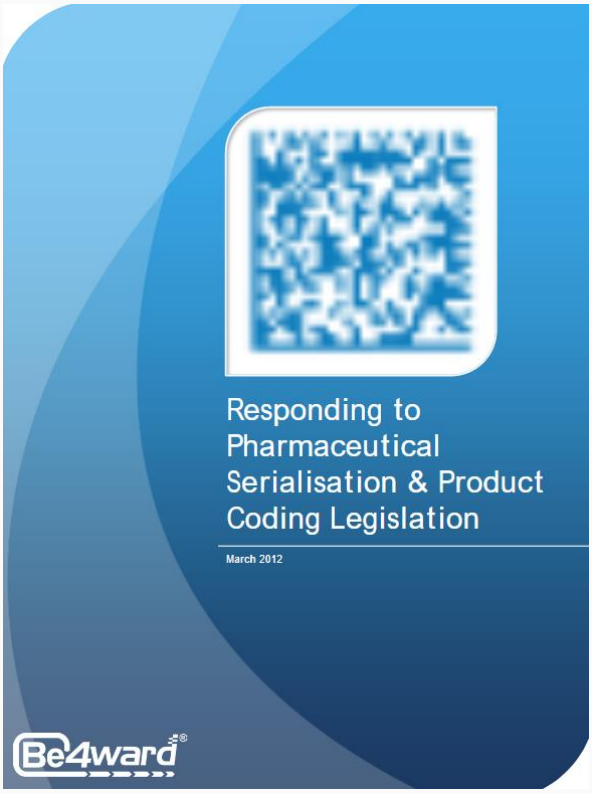
ENSURING EFFECTIVE TRANSLATIONS – BRIEFING YOUR TRANSLATION PROVIDER

By Andrew Love - VP of Be4ward

Continuing this series of blogs expanding on Ensuring Effective Translations, the next set of tips are to help you make sure that the information you are giving to your service provider is well organised and clear.

>> Read it offline

Read it online



Responding to Pharmaceutical Serialisation & Product Coding Legislation

EXECUTIVE SUMMARY

Stephen McIndoe
Andrew Love

Pharmaceutical product serialisation legislation is being developed and approved across the world to ensure patient safety and prevent fraud. Achieving this across the supply chain is a major and very costly undertaking. Failure to comply with these legislative requirements will mean that pharmaceutical companies will not be able to sell products in the affected markets.

Serialisation legislation requires that every product pack is uniquely identified and registered in an external agency database, together with information about the product contained in the pack. Depending on the particular legislation, it may also be necessary to update the external agency database with product movement and change of ownership information, a significantly more complex requirement.

Whilst some pharmaceutical companies understand this legislation and have a clear strategy and program of capability implementation under way, others do not.

This white paper outlines the requirements of serialisation and related product coding legislation, discusses what needs to be done to address it and identifies some next steps to effectively manage the risk.

Read the Executive Briefing to learn more

>> Read it offline

Top News Picks

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

We must prepare supply chains for future COVID-19 vaccines and therapeutics

By TOM WOODS for World Bank Blogs

Nothing would undermine delivery of successful COVID-19 (coronavirus) vaccines and therapeutic treatments faster than the emergence of fake vaccines.

Click here to read the article

Global anti-counterfeit packaging market to grow to $17.47 billion

By Hannah Balfour (European Pharmaceutical Review)

Growth in the anti-counterfeit technologies market will be particularly large in the pharma industry due to increasing awareness around health and safety, says report.

Click here to read the article

New guidance to ensure medicine label claims are genuine

By Tim Sandle in Health

The U.S. Food and Drug Administration (FDA) has recently released new guidance concerning drug labeling. This is an important area to crack down on, as misleading claims can lead to patient harm.

Click here to read the article

Are You Prepared For The U.S. Enhanced Drug Distribution Security (EDDS) Requirements?

By David Colombo, director, Life Science Advisory, KPMG

The Drug Quality and Security Act (DQSA) was signed into law almost seven years ago on Nov. 27, 2013. Title II of this Act, known as the Drug Supply Chain Security Act (DSCSA), established a set of requirements and phased compliance dates for prescription drug manufacturers and other participants in the distribution chain to address vulnerabilities in the supply chain and to facilitate the tracing of certain drugs throughout the supply chain.

Click here to read the article

Proofreading problems: a sandwich worth doing time for...

Another unfortunate example of a proofreading fail. Have you seen other examples? Please share them with us!

Executive Briefing: read offline

Responding to Pharmaceutical Serialisation & Product Coding Legislation

Pharmaceutical product serialisation legislation is being developed and approved across the World to ensure patient safety and prevent fraud. Achieving this across the supply chain is a major and very costly undertaking. Failure to comply with these legislative requirements will mean that pharmaceutical companies will not be able to sell products in the affected markets.

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SERIALISATION PRESENTS A SIGNIFICANT PRODUCT SUPPLY RISK WHICH NEEDS TO BE MANAGED CAREFULLY

Pharmaceutical product serialisation legislation is being developed and approved across the World. Failure to comply with these legislative requirements will mean that pharmaceutical companies will not be able to sell products in the affected markets.

The primary objectives of serialisation legislation are normally targeted at helping to resolve two issues:

- Reduction of counterfeit or falsified medicinal products.

- Reduction in reimbursement fraud.

Therefore, the legislation normally covers prescription pharmaceuticals and products which are reimbursed by governments. Previously, it had been believed by some that vaccines and other cold chain products would be exempt from such legislation; however this no longer appears to be the case.

Only a few years ago, many would have argued that any talk of serialisation legislation was more rhetoric than reality and that any serious implementation requirements were way over the business strategy horizon. Therefore many chose to delay addressing the issue.

Today the picture is very different; several countries have implemented serialisation legislation, including more recently the European Union. In some cases the legislation is in force today, in others the timelines are still unclear, but within the business planning strategy horizon.

Companies need to have a clear strategy for tackling serialisation and product coding legislation that will ensure that any risks to product supply are adequately mitigated.

As we look across companies today, we see a broad range of readiness. At one end of the spectrum, there are some organisations of all sizes that are already capable of serialising significant proportions of their product range and indeed do so today. More worryingly, at the other end of the spectrum, there are organisations that have not tackled serialisation to any great extent, do not fully understand it and certainly have no coherent strategy to deal with the supply risks it presents.

AN INTRODUCTION TO SERIALISATION REQUIREMENTS

We will break serialisation legislative requirements down into four elements to help explain it:

- Unique Identification
- Product Information Notification
- Authentication

- Track & Trace

Unique Identification
All serialisation legislation requires one or more levels of packaging to be uniquely identified with some form of “licence plate” or serial number. Furthermore, in all recent legislation, this identification must be applied to packaging using some form of machine-readable carrier.

In current legislation, the lowest level of packaging requiring serialisation is the smallest saleable unit, typically the secondary pack. As will be discussed later, some legislation also requires higher levels of packaging and shippers to be serialised as well.

Ultimately, serialisation of primary packaging (e.g. blister pockets, vials) and in some cases (e.g. tablets) the product itself may be required, as many would argue that this provides the best protection to the patient. Whist some regulators are discussing this, few are indicating imminent legislation.

There are broadly two approaches to ensuring that serial numbers are unique that are currently adopted by legislation.

Market Uniqueness
In this model, an external agency manages all serial numbers for a particular market or region. They issue serial number blocks to manufacturers (and potentially other supply chain partners), who would then manage the application of those numbers to product packaging.

UNIQUE IDENTIFICATION = (UNIQUE NUMBER ISSUED BY EXTERNAL AGENCY)

In this model, a manufacturer will typically require a serial number [request and allocation management system] to ensure that enough serial numbers are available in the right locations to enable manufacture.

Product Uniqueness
An alternative model uses a combination of product code and serial number

to achieve uniqueness.

UNIQUE IDENTIFICATION = (PRODUCT CODE) + (SERIAL NUMBER)

Product codes, such as the internationally recognised Global Trade Identifier Number (GTIN) are unique. Therefore, in this type of scheme, the uniqueness of serial numbers need only be managed across all product of the same Product Code.

Given that product codes are normally unique to a single manufacturer, the management of serial numbers for a product can then become the entire responsibility of the individual manufacturer. Typically this simplifies matters as it is not necessary to ask an external agency for groups of serial numbers and it offers the opportunity for simpler rules-based serial number allocation and management to individual manufacturing facilities.

Having established which packaging levels need to be serialised and the method of creating and managing unique identifiers or serial numbers, we will now discuss the information that needs to be applied to the packaging and the mechanism by which this is achieved.

Information Applied to Packaging

Often, the information required to be applied to the packaging is not limited to the unique identifier or serial number described above. Frequently, additional information such as [Batch/Lot Identifier] and [Expiry Date] are also required to be included in the machine readable carrier. Often, if not already present, text describing this information must also be applied to the packaging.

This additional information allows people in the downstream supply chain to make use of the information to improve the efficiency and effectiveness of their processes without the need to obtain information from any other source.

As an example, dispensaries can scan the machine readable carrier, obtain information about the product contained within the carrier and compare this electronically with the prescription to help reduce dispensing errors.

Machine-Readable Carriers

There are many different ways in which information can be placed on a pack in order that it is machine readable.

Where serialisation legislation is concerned, two methods are typically currently mandated: linear barcodes and/or 2D/Datamatrix Barcodes. Radio Frequency Identification (RFID) tags have also been extensively discussed, but at the time of writing had not been mandated.

Figure 1 discusses each of these carriers in more detail.

Product Information Notification

Typically, once product packaging of one or more levels has been uniquely identified, this information, together with other information related to the product and manufacturer is passed to an external agency database.

This information in this database is then used by the downstream supply chain and other agencies as described in the following sections.

The triggers and grouping of the information transfers will vary according to the specific requirements of the legislation. In the simplest of models, the information can be transferred at, or around the time when the product packaging batch has been completed.

Figure 1: Principle Carrier Types

Type		Advantages	Disadvantages
Linear Barcodes		• Low cost • Readable by most scanners in the supply chain today	• Large • More difficult than 2D codes to apply to packaging • Not robust to partial damage • Must be read with line of sight
2D Barcodes		• Low cost • Small • Robust to partial damage	• Must be read with line of sight • More complex and costly readers than Linear Barcodes
RFID Tags		• Can be read without a line of sight	• High unit cost • Complex technology • Requires complex and costly reader technology

Authentication
Authentication is a term often used to describe the following process of checking the legitimacy of a product using it's serialisation.

One of the primary purposes of serialisation is to enable individuals in the downstream supply chain scan a product and compare the information on the product packaging with the information stored in the external agency's database. If the two sets of information match and it is evident that the product has not been tampered with, then it will be highly likely that that the product is legitimate.

As an example, a patient might scan a product pack with a smart phone using it's in-built camera. Using an application, the smart phone would then request information related to the unique identifier contained in the machine readable code and display it to the patient. The patient would then compare this information to the text information contained on the packaging. If everything matched and the tamper evident sealing was still intact, the patient could have greater confidence that the product was legitimate.

A number of serialisation legislative models stop at the requirement for a means of Authentication. It appears that the recent European Union falsified medicines legislation 2011/62/EU is one such example. Many would argue that this level of serialisation provides a sufficiently improved level of protection against falsified products and fraud that is sufficient, at least for the current round of legislation.

Track & Trace
Track and trace legislative models attempt to further improve the protection against the entry of falsified medicines into the legitimate supply chain.

Typically this is achieved by also requiring every change of ownership (and potentially location) of product to be recorded in the external agency database. Such legislation then also requires purchasers to verify the legitimacy of the product they are receiving by ensuring that the external agency database confirms that the seller had legitimate ownership of the product prior to sale. Rules are also be required in the external agency

database to ensure that the same product was not introduced illegitimately into the supply chain, or sold more than once from any single owner.

This is a similar model to that used in many countries to control the legitimate buying and selling of motor vehicles, which also present a significant threat to the health and safety of the public if they are not legitimate. Many such models adhere to the following basic principles. Each car is identified by a unique licence plate. When a seller sells a motor vehicle, they have to complete a sales transaction which is registered in the transport agency's database stating which vehicle (licence plate) they have sold and to whom. When a buyer purchases the motor vehicle, they register their ownership with the same agency and indicate who they purchased the vehicle (licence plate) from. The external agency database also contains other information that helps confirm the identity of the vehicle to anyone concerned, such as make, model, colour. This information is also used by buyers and sellers to confirm the legitimate identify of individual vehicles. If the sale and purchase information matches then all is ok. If not, then investigation activity is triggered.

These additional track & trace requirements necessitate two very significant additional elements to be implemented over and above the Authentication serialisation model:

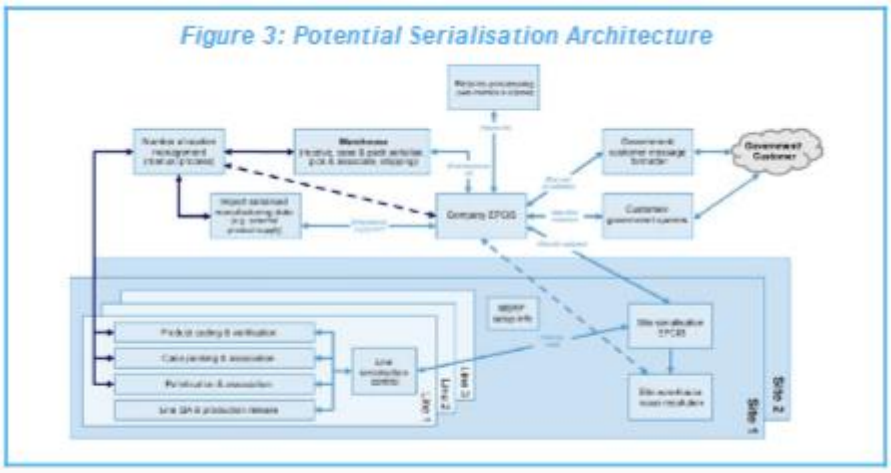
1. Many, if not all, supply chain nodes handling product will need to be equipped to scan product and relate the unique identifier information to purchase, sales and other transactions and then communicate it to the external agency database. If they break product shippers down, they may also be required to serialise new shippers.
2. To make (1) practical, many if not all levels of packaging shippers (e.g. bundles, cases and pallets) need to be serialised and the physical relationship between a shipper and it's serialised contents built, communicated and maintained in the external agency's database.

Element (1) is required to track the purchase and sales transactions down to the individual uniquely identified pack. For example, whenever a sale is made, all products which are physically changing ownership would need to

be identified and the associated sale information updated in the external agency database. This requires the location in the supply chain handling the product at the point of sale to physically identify all the product being sold, down to its unique identifier. This is normally achieved by incorporating serialisation technology into the order processing and picking activities at a distribution location.

Element (2) is required to avoid the need for every such distribution location to break open all shippers and identify all uniquely identified packages within. A situation which would quickly bring the product supply chain to an effective halt.

Figure 2 outlines such a track and trace model



Reverse and Abnormal Process Flows
It should be noted that reverse product flows and abnormal events can add significant complexity to the design of the business processes and IT systems required to manage serialisation.

Product Coding Legislation
Product coding legislation requires manufacturers to apply machine readable codes to product packaging. These codes typically contain information pertaining to the product, batch and expiry information, but no unique identifiers. Whilst this is not serialisation in of itself, the solutions that must be implemented to meet these requirements can be significant building blocks

for any future serialisation implementation if they are specified and selected appropriately.

Therefore, many organisations choose to manage the response to this product coding legislation together with serialisation to ensure the best long-term solutions are implemented.

Standards
It will be evident to you by now that serialisation requires many different stakeholders to receive, create, read, process and transmit information related to serialisation.

For this to be achievable within the scope of a particular piece of legislation, standards must be defined an adhered too.

Many would further argue that, in order to avoid unnecessary complexity and cost, these standards should be international.

OPPORTUNITIES
Whilst the primary objective of many organisations will be to meet the requirement of the new legislation, there are also opportunities which will result from this.

From a commercial perspective, for example, serialisation and product coding can be used to provide additional services to patients by linking information and services to the coding on the pack through such things as cell phones. This provides opportunities to improve patient safety, through the likes of improving adherence; increase the knowledge about patient and product use and improve relationships directly with patients.

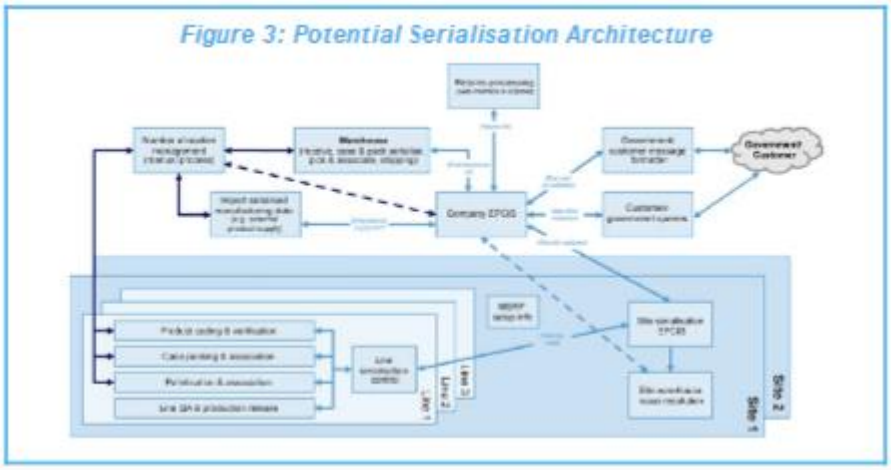
From a supply chain perspective, particularly in track and trace models, serialisation capabilities can be harnessed to provide improved supply chain visibility, leading to improved customer service and efficiencies.

IMPACTS OF SERIALISATION LEGISLATION
Serialisation legislation will require new capabilities to be implemented

across many different functions of a typical company.

The more obvious impacts include:

- Packaging operations, where serialisation will have to be applied to product packaging at one or more levels.
- In the more complex serialisation models, this operational impact will extend into the distribution 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.
- Particularly in the more complex track and trace models, significant IT capabilities will be required to manage serial numbers and track information related to the product and it's movement.



However, the impacts go beyond these into areas such as regulatory affairs, commercial and others.

WHAT NEEDS TO BE DONE

Companies are faced with several specific issues when managing serialisation related legislation, these include:

Identifying and interpreting the emerging and evolving legislation.

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

This is further compounded when considering the time lines allowed in the legislation. History has shown that timelines are often vague and subject to change. However, when implementation dates are finally set, they often do not allow enough time for robust implementation.

Given the uncertainties in requirement and timing, organisations need to ensure that 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.

Understanding the full impact of these multiple pieces of legislation on the company and product supply chain.

We have already discussed the potentially broad impact of the legislation 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.

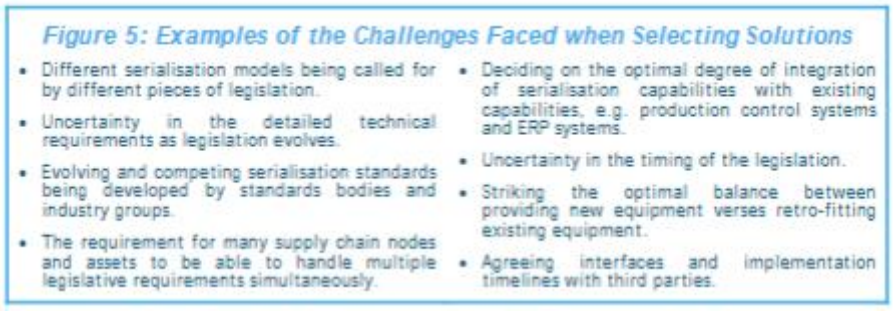
A further challenge is that the multiple pieces of evolving legislation will often impact many of the same capabilities. Understanding these potential impacts and their likely evolution over time is key to ensuring effective solutions are defined and implemented in a timely manner.

Defining optimal solutions and implementation plans which strike the optimal balance between ensuring product supply and the caution that is prudent with this evolving legislation.

There are often a number of supply chain configuration and technical options

that can be brought to bear to deal with particular serialisation legislative requirement. Short term tactical options have to be weighed against longer term strategic solutions. *Figure 5* highlights some of the challenges that need to be addressed when defining optimal solutions.

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 we mean the risk that, as so often is 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 costs and forcing companies into non-compliance.



Understanding the immature and evolving solution supply base and selecting appropriate implementation partners.

Serialisation legislation is relatively new to the Pharmaceutical industry and therefore the solutions available from the supply base are correspondingly immature and in many cases evolving. Supplier selection will often be the start of a very long relationship, as solutions that are initially implemented will need to be supported and adapted to new requirements over time. There have already been several examples of suppliers that have come and gone as legislation has evolved or been delayed. Understanding the supply base and choosing the most appropriate suppliers will be critical to long term success.

Defining complete requirements covering all aspects of the solution’s lifecycle and then realistically judging the supplier’s ability to meet these requirements also presents challenges.

Resourcing implementation projects with sufficient serialisation specific knowledge to minimise the risk of wasted resources, delays and implementation failure.

The specific challenge during the design, build, test and implementation phases of solution projects is to resource them with sufficient serialisation subject matter skills and knowledge to avoid common pitfalls, reduce wasted effort and the risks of delay and solution failure.

Organisations need to plan for these resource requirements and build sufficient capabilities internally and secure access to sufficient external resources where appropriate.

CROSS FUNCTIONAL GOVERNANCE IS CRITICAL

Given the cross-functional and cross-organisational nature of the impact of serialisation legislation, coupled with the significant product supply risk it presents, many organisations establish a cross functional governance team to ensure that:

- Decision making is taken with all impacted parties, at the right levels in each of the organisations involved.
- A “Target Response” is defined that specifies what the organisation must achieve and by when, given the current state of legislation and the organisation’s considered view of how and when capabilities will be required.
- Changes to the Target Response are carefully managed and cascaded to all impacted groups.
- Appropriate cross-functional and cross-organisational resources are mobilised to address the issues in a coordinated and timely manner.
- Timely approval and funding of the program of activities is achieved.
- Progress, priorities, risks and issues are managed in an optimal way for the organisation as a whole.

SOME LEARNING

The authors of this White Paper have developed strategy for, established

and then operated serialisation capabilities for one of the world's largest pharmaceutical companies. Following on from this they have gone on to help a number of companies do the same. The journey in California, Europe, Turkey, India, China and elsewhere has been very informative. Some of the key learning points include:

- Recognise the significant supply risk and manage it accordingly, establishing senior cross functional governance early.
- Mobilise your regulatory, legal and technical teams to establish effective access to, and interpretation of, the emerging legislative and technical standards.
- Actively interpret the evolving requirements and standards for the organisation using tools such as the "Target Response" (described previously).Establish a programme of activity to build organisational and extended supply chain capability.
- Be realistic about the emerging nature of these capabilities and build in adequate time and resource to adequately test and iterate solutions.
- Design serialisation activities to closely couple related actions to minimise the possibility for errors due to abnormal events.
- Design for both the normal processes and the regularly occurring non-standard events to avoid product supply quickly grinding to a halt.
- Ensure cross-functional teams are established to carefully design the interfaces between departmental and organisational boundaries.
- Ensure that adequate time is allowed for packaging design changes to be made to accommodate serialisation features between departmental, organisational and systems boundaries.
- Be cautious about suppliers who have little practical experience in this area.

WHERE TO START

It is highly likely that one or more parts of your organisation are already working on this issue, perhaps in a coordinated way, perhaps not. Initially, we would recommend continuing this work until the appropriate course of action has been decided.

We would recommend a small and focussed piece of work which has the following objectives:

- Understand the issue as it relates to your business.
- Understand the likely impact across your organisation.
- Identify, educate and mobilise an effective cross functional governance team.
- Establish an effective legislative monitoring capability.
- Define an initial “Target Response”.
- Define a plan of action.
- Identify any initiatives that are currently under way and define how they should proceed.
- Understand the high level budgetary implications.

From here, a programme of activity can be managed by the governance team to effectively manage the legislative risk.

How can Be4ward help

The Be4ward team has many years of experience in managing and implementing solutions for serialisation for some of the world’s largest and smallest pharmaceutical companies.

We offer a range of services to assist our clients in the following areas:

- Serialisation education.
- Current situation evaluation.
- Strategy development.
- Governance establishment and membership.
- Legislative interpretation.
- Implementation program design.
- Requirements definition.
- Solution design.
- Supplier selection.
- Project implementation.

- Solution validation support.

As a first step, we would welcome the opportunity to discuss your situation and identify any immediate areas in which we might be of assistance.

About Be4ward
Be4ward helps Pharmaceutical, Biotech and other Healthcare companies and their supply base to improve patient safety and drive additional value from their product range. They do this through a range of products and consulting services.

Visit us at www.be4ward.com or contact us at enquiries@be4ward.com.

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Excellent Packaging Artwork Capabilities part 5 – Leadership, governance and technology

In part 4 of my blog series on how to create excellent packaging artwork capabilities, I looked at the third of our defined processes, Supporting Processes and the influencing aspects of organisation design. Here in the final part five I will look at our final two capabilities: the importance of establishing the right inclusive leadership and governance and the role technology plays in establishing artwork capabilities.

Leadership and Governance

Given the cross-functional and cross-organisational nature of the artwork capability, establishing the right inclusive leadership and governance is key to the long-term success of the capability. All stakeholder groups involved in the delivery of the artwork capability need to contribute effectively or the whole process will fail. Therefore, all parties must buy into their role in the

process and actively contribute to it. This will rarely happen if they are simply passive bystanders in the design of the capability or the delivery of the resulting activities.

The role of an Artwork Governance Team

We would recommend establishing a cross-function governance team to steer the establishment, ongoing delivery and development of the overall artwork capability. This governance body should include membership from all stakeholder groups involved in the process, including, where appropriate, external service providers.

It is all too easy when forming and managing governance teams to focus on the steering and decision-making aspect of the activity. If you are not careful, this may result in the leadership responsibilities of the team being overlooked. The governance team needs to ensure that they provide leadership to the artwork function in a number of distinct ways. Firstly, they need to ensure that a vision and strategy for the artwork capability is developed, agreed across all impacted stakeholders and communicated effectively to the broader organisation. Secondly, they need to ensure that the journey to achieve this vision is structured and managed effectively and that progress is communicated to the wider organisation. Thirdly, the leadership of the governance team needs to manifest itself in decisive decision-making that supports the vision and goals of the artwork capability. Finally, the behaviours the leadership display need to actively model and support the key cultures that underpin the successful service delivery.

To support these leadership activities, some organisations purposefully put in place a number of key roles:

Senior sponsor – a senior member of staff who will represent and support the overall artwork capability at the highest levels in the organisation.

Governance team chairperson – the leader of the governance team who ensures that the governance team activities are managed effectively.

Artwork process owner – an individual who is responsible on a day-to-day basis for ensuring that the end-to-end artwork process operates effectively and that any improvements to the process are appropriately designed.

With all of this in place on an ongoing basis, the artwork capability should remain effective and appropriate for an organisation over time.

Technology

Technology is a necessary and useful part of any packaging labelling and artwork capability, indeed it is practically impossible to operate an artwork capability today without some elements of technology.

Technology helps address many issues which can lead to improvements in compliance, performance and cost. Some of these issues include:

- Eliminating human error, particularly prevalent in transcribing information and in proof reading
- Ensuring everyone has the right, up to date information available to them when they need it
- Ensuring process adherence
- Aiding coordination of the different people involved
- Helping individuals manage their own activities better
- Reducing lead times
- Reducing cost

Before I go on to discuss any specific IT capabilities, let me just pause to cover some of the potential downsides of technology. Before selecting and implementing any technology, the full implications and costs should be weighed against the benefits. Some of these costs include:

- Initial and ongoing cost of tools and software
- Systems maintenance and support capabilities
- User education, training and support capabilities
- Impact of the technology on other business processes

For the purpose of discussion here, I will break down the packaging, labelling and artwork related technology into a number of sub-groups. I will briefly describe each of them and you will find a more detailed discussion on each of them in our book, *Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities*. You should be aware that the solutions

available from different vendors often provide functionality that crosses two or more of these areas and I expect this trend will continue over time.

Artwork Creation: the tools necessary to create such things as documents, artworks, drawings, 3D visualisations and the associated components such as barcodes, Braille etc. generally, this technology is available off the shelf. The principle issue in implementing these tools is deciding and controlling which of the many configuration options are used.

Document Management: the tools necessary to securely store documents, ensure versions are managed effectively and that audit trails are maintained.

Translation Management: the tools necessary to efficiently and effectively manage the creation, storage and use of translations. Companies use everything from simple documents through to complex and sophisticated translation management solutions in this area.

Image Management: the tools necessary to ensure that what the user is looking at is a true representation of the underlying document. This includes such things as pdf creation, printing, electronic image presentation and colour management.

Collaborative Review & Approval: the tools necessary to allow individuals and groups to review individual documents, create and manage comments and ultimately securely approve documents. This area would include such things as electronic signature management.

Proofreading: tools that help users to proofread documents and their associated elements such as barcodes and Braille. Whilst very useful in reducing errors in artwork, it should be remembered that these tools are only aids to skilled proofreaders and need to be used with caution.

Change Control & Authorisation: the tools necessary to manage the definition and authorisation of changes in a compliant environment. The change control aspects of labelling and artwork changes will often be managed as part of a larger corporate change control system.

Bill of Material Management: whilst often not considered part of the labelling and artwork suite of tools, bill of material management systems are key to the success of labelling and artwork management at either end of the process. Initially, they are key in ensuring an accurate and comprehensive

impact assessment is carried out. At the end of the process, they are key to ensuring that the changed packaging components are implemented in a controlled way into production.

Planning and Work Management: tools such as workflow technology that allow activities to be planned and routed to the right individuals at the right moment. More sophisticated versions of these tools will have the ability to manage large numbers of individuals, locations, work teams and separate organisations.

Performance Management: the tools necessary to gather and report performance information across the end-to-end capability. Some organisations will use corporate business intelligence tools for this.

Forecasting and Budgeting: the tools used to help forecast workload, plan resource capacity and financial budgets.

Don't forget that many of these technology elements will need to be validated as the implication of their failure could impact artwork quality and therefore patient safety.

I will close with a word of caution when specifying, selecting and implementing technology which I have learned the hard way from experience. Many of the technology elements I have described have subtle interactions and dependencies with each other. Unless these dependencies are fully understood, it is very easy to make a change in one area that has an unforeseen and detrimental impact in another.

To help you with your artwork improvement programme, you can also find useful information in our book Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities

Should you have any questions about this or any other of my blogs, or would simply like to request a copy of any of our publications, please don't hesitate to contact me directly on my email: stephen.mcindoe@be4ward.com

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Ensuring Effective Translations – Translation specifications

Andrew R Love

As we hit the halfway mark in this series of blogs covering the basics on Ensuring Effective Translations, the next set of tips guide you through establishing a set of standards for working with your translation provider.

Translation standards

Two notable standards for translations are: the European translation standard (CEN EN 15038) and the American translation standard (ASTM F 2575). Although these were developed independently, they fit together well. They both provide a set of rules and guidelines for how to approach and build your translation. The standards provide a wealth of valuable information drawn from numerous experts with significant experience of the topic. They cover such areas as:

- The selection of people involved and how to ensure the professional competency of translators and reviewers
- The requirements of quality management systems
- The need for effective project management
- How to manage the relationship with your translation service provider
- Processes and procedures you should implement for translating, checking, revising and reviewing to ensure effective translations
- The technical and linguistic aspects you should consider
- CEN EN 15038 also includes a series of annexes providing further information on many of the detailed requirements.

The content of a specification

As discussed already in this series, preparation is critical if you wish to receive an accurate translation. When purchasing any product or service it is essential that you have clear requirements defined that can be easily communicated to your chosen supplier. Typically, this would be called a specification. In the haste to deliver a translation quickly there is often a desire to cut corners at this stage and start translating before your

requirements are fully thought out. This can be imprudent as this risks a greater degree of rework at the back of the process to sort out issues that weren't considered properly in the first place. This often leads to greater time being required for the project. The adage 'garbage in = garbage out' is applicable here.

The annexes in CEN EN 15038 list the typical contents of a specification and include:

- Source content and language
- Purpose of the translation
- Project registration/identification details and contacts
- Deadline
- Price and contractual terms
- Subject area and type of text
- Format (word processing file? XML?)
- Volume (how many words, characters, etc.)
- Target language and regional variation
- Key process steps to be followed and associated responsibilities
- Reference materials and style guides to be used
- Measures

Once you have defined your specification, it is then important to share with key stakeholders, reviewers and your service provider to ensure they all understand and agree on the content. This will help reduce the number of queries or changes you get as the document goes through review cycles. Your target should be right first time.

In the next blog we will look at the sixth step – Briefing your Translation Provider, examining how you instruct the translation provider to undertake the project you want translated.

Should you have any questions about this or any of my other blogs, if you would like to discuss the artwork processes within your company 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

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Ensuring Effective Translations – Briefing Your Translation Provider

Andrew R Love

Continuing this series of blogs expanding on Ensuring Effective Translations, the next set of tips are to help you make sure that the information you are giving to your service provider is well organised and clear.

Ensure there is a comprehensive instruction to the translation provider
The preparation of the specification discussed in the previous blog is the starting point for briefing your service provider. Key things for the service provider are an understanding of the target country, language and dialect(s), the audience, the timelines, the formats and key instructions that you want followed. This is all part of your specification.

Keep your service provider up to date with your project and any potential changes that might happen. This allows them to prepare and be more responsive.

Organise your file submissions
To ensure the most effective use of your service provider, don't just send through all of the materials you may have. Make sure that you have organised your materials to help them. Include all the relevant files in a logical order and don't include any materials that you don't want translated. This saves the translator time and effort by not having to sift through materials looking for relevant content or translating material that you don't need. If the translator has to sort your documentation it will likely delay your project.

Also provide files in a suitable format. Whilst most translation service providers can handle many formats it takes longer to translate from hard copy.

Tell the translator what it's for

Different types of document need different styles of translations. A technical article is not a travel brochure and a press release requires a different style from a legal contract. It is therefore essential to be clear with your translation provider what the translation is for and your expectations for tone, word choice, sentence length, phrasing and degree of formality.

You also need to inform your translation provider about your target audience. Different age groups and education backgrounds in your target audiences will require different approaches and tone.

If your translation is a technical subject, it is important that your translation provider understands the subject. They need to articulate the subject accurately in a way that is clear and readable to the audience, therefore, translators familiar with the subject are likely to produce better text.

An experienced translator is likely to ask for such information and the different requirements in quality have a direct effect on the cost and completion times. For many translations, the successful expression of the meaning is more important than an exact translation of the source text, so the translation provider has to make difficult decisions on the style and meaning. As your translation provider gains understanding of your business strategy, products, audiences and preferences, the better their translations will be. If your translation provider is not comfortable with your subjects and audiences, it is time to change your supplier. You need your foreign language text to have the maximum impact and a provider that can deliver that.

Provide all the details to your translator

The more information your translation provider has, the better prepared they can be and the better service you will receive. The greater the clarity of the brief, the more chance there is of choosing a translator who has the appropriate experience in the area.

We have discussed already ensuring the translation provider knows the intended audience, use, style etc. of your translation, but you also need to think about the quality criteria that have to be met. Some of the questions you need to consider are:

Will a second translator be involved in the editing or proofreading?
Is it the client's responsibility, or will a separate reviewer be assigned?
The quality of the translated text will be much better if it is reviewed and enhanced by a second translator and in some cases this quality control is a must. However, it may cost extra or have an effect on deadlines so this must be agreed upfront with your translation provider.

Is the overseas representative for your company going to have a look at it as well?
If yes, at what stage of the process would this take place?
Who is responsible for managing this, the translation provider or yourself?

What will be the format of the final file (PDF etc.), and how will the translation company deliver the file?
Who will ensure that all corrections are incorporated and how many revision cycles are included in the price?
How do you want to communicate revision requirements to the translation provider?

Finally, it is worth considering what happens to the text after it has been translated. If post-translation work, such as typesetting, is required for the project, it is possible for some translation companies to undertake this as well. Similarly if the translation is required for recorded speech, the translation company may have services to provide this.

In the next post we will look at the seventh step – Preparing Your Translations; tips to ensure that the translation provider has everything in order.

Should you have any questions about this or any of my other blogs, if you would like to discuss the artwork processes within your company 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

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