See the latest business and healthcare industry news from Be4ward.
Featuring: Serialisation | Packaging | Labelling & Artwork | Supply Chain

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 a new article in our series on the topic of Covid-19 vaccines and the healthcare supply chain. This latest article looks at the threat of cybercrime to the supply chain and the tactics employed to help battle this criminality.

As always, we share our consultants' thoughts and knowledge via a series of blogs, including the next part of our **Ensuring Effective Translations** series, where we look at Approving the Translation - with two important considerations; *who will approve the translation?* and *how will this approval manifest itself?* 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: ***Avoiding the supply risk from serialisation with CMOs*** capturing some of our learnings from many years spent implementing serialisation with pharma companies and CMOs.
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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Go to Executive Briefing

Go to Top News Picks

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Company News

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Countering Covid-19 Criminality: Battling Pharmaceutical Cybercrime

Grant Courtney | Be4ward Principal Consultant

"Cyber-criminal organisations haven't lost time in exploiting the Covid-19 pandemic. If anything, they've been quick to shift towards a new area of growth and profitability, one that is driven by the fear and uncertainty that accompanies the pandemic-related morbidity and mortality."

Seeing the very gradual emergence of vaccine versus virus is certainly giving much needed optimism. Sadly, along with the legitimate distribution of the vaccine, we're also seeing a surge in illegitimate online sales of the various vaccines and therapeutics.

How can we protect this most precious of supply chains?

This latest article on the topic of Covid-19 vaccines and the Healthcare supply chain, highlights some of the techniques that have been adopted to help suppress the rapidly increasing problem of online counterfeit and falsified drug sales.

The author is Grant Courtney, a leading healthcare industry consultant and industry-recognised expert adviser on digital brand protection and product traceability. Grant has written before about the importance of using established traceability standards to secure the legitimate vaccine supply chain. In this subsequent article, Grant examines the cybercrime challenges the world faces at the advent of a Covid-19 vaccine, and how they're being addressed with a two-pronged offensive of public education coupled with mechanisms to police the online market place.

Read Article Here

Date for the diary

Hopefully 2021 will see face-to-face meetings and live conferences happening once again. After moving online in 2020, *Making Pharmaceuticals Exhibition and Conference* is planning to be back as a live event this year, and Be4ward is booked to attend with a selection of speakers.

We'll share further information on date, time and tickets when the ticket bookings open.

Visit Making Pharma

Industry News

Be4ward

GS1 Digital Link

With just one simple scan, everybody finds the information they're looking for. This is possible by using the unique GS1 codes in web addresses. You can easily connect your product to information on the internet. All products all over the world are now connected to the internet using the GS1 Digital Link standard. What can GS1 Digital Link do for you? This great video from GS1 Nederland introduces the world of possibilities with web enabled packs.

Watch the video

Company Blogs

Be4ward

ENSURING EFFECTIVE TRANSLATIONS – APPROVING THE TRANSLATION

By Andrew Love - VP of Be4ward

As we approach the end of this series of blogs expanding on *Ensuring Effective Translations*, the next set of tips are to help you make sure that the final formal approval of the translation goes as planned.

Once the translation reviews have been completed and all edits are agreed, the final translation needs to be approved.

There are two things to consider at this point; **who will approve the translation?** and **how will this approval manifest itself?**

Read it offline

Read it online

COUNTERING COVID-19 CRIMINALITY: BATTLING PHARMACEUTICAL CYBERCRIME

By Grant Courtney - Principal Consultant

Perhaps the most eagerly anticipated therapeutic innovation in the history of time, the first effective Covid-19 vaccine is now rolling off the production line and out to the world. Producing and successfully distributing an effective vaccine has signaled a significant step towards addressing a global pandemic that has crashed economies, curbed freedoms, claimed close to 1.5 million lives worldwide and sickened more than 63 million. Projecting into the not-too-distant future, the fully vaccinated will be able to enjoy greater freedoms; to interact, to travel, to work and to return to some sense of normality. That the ticket to these freedoms is potentially contained in a small glass vial, makes these vials at high risk of falsification and counterfeiting by criminals seeking profit from the misfortune and fear of others.

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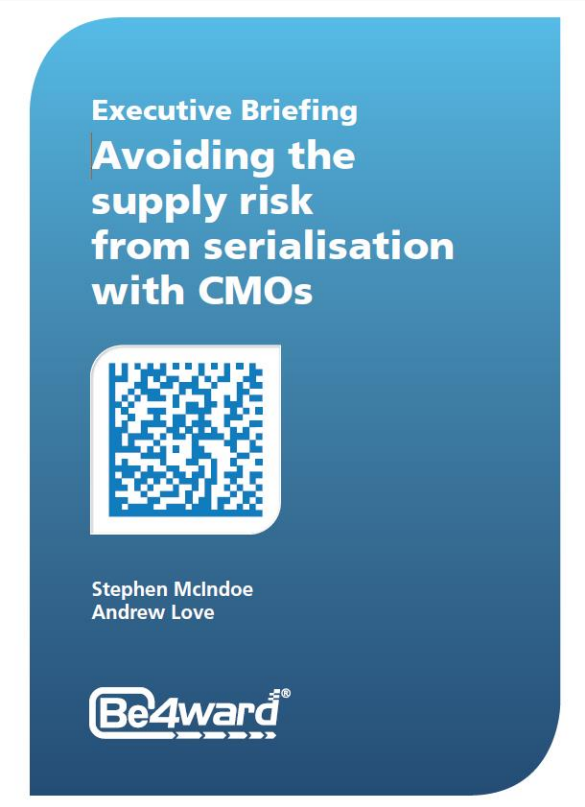
Executive Briefing

Be4ward



Avoiding the supply risk from serialisation with CMOs

INTRODUCTION

Stephen McIndoe
Andrew Love

For many Pharma companies, the use of contract manufacturing organisations (CMOs) to package commercial product is an integral part of their supply chain. Indeed, for virtual companies, it may be the only way their products are packaged.

Serialisation legislation in the US, EU and many other countries means that, with out the successful and timely implementation and integration of CMO

serialisation capabilities, Pharma companies will no longer be able to supply product.

The complex, evolving, immature and increasingly resource constrained area of serialisation means that the risk of significant supply interruptions are high.

Be4ward has been implementing serialisation with Pharma companies and CMOs for many years. We have written this document to capture some of our learning throughout that journey and hope it will be useful to you, the reader.

Key learning 1 Be realistic about the real flexibility the CMOs have

Key learning 2 Be realistic about what CMOs are really going to pay for

Key learning 3 Understand the CMO's decision making process

Key learning 4 Be realistic about your CMOs view of your importance to them

Key learning 5 Use risk management to focus resource application

Key learning 6 Make sure you assess each CMOs capability and capacity to deliver

Key learning 7 Make sure you have sufficient Plan Bs

Key learning 8 Ensure you have a cross-functional team on this from day 1

Key learning 9 Don't believe that the software vendors can sort this out for you

Key learning 10 Standard ways of working are valuable, but only guidance for wise men

Key learning 11 Make sure that there is enough of the right resource engaged on the problem

Key learning 12 Make sure your internal RACI is clear

Key learning 13 Make sure everyone understands how this is going to work

Key learning 14 Ensure there is a clear data and messaging model in place

Key learning 15 Ensure there are repeatable test protocols in place

Key learning 16 Separate capability implementation from product cut-over

Key learning 17 Treat this as a program (unless you only have one CMO)

Key learning 18 Recognise and cater for ongoing change

Read the **Executive Briefing** to learn more

Read it offline

Read it online

Top News Picks

Be4ward

US govt prepares for COVID-19 vaccine fraud surge

By Securing Industry

With the first COVID-19 vaccines now nearing approval, the US government is preparing a crackdown on an anticipated spike in falsified and unauthorised medicines by fraudsters.

Click here to read the article

Companies are racing to build digital passports for people to prove they've had the Covid vaccine

By Kif Leswing for CNBC

People who get vaccinated against Covid-19 at Dodger Stadium leave with inoculation against the virus, a band-aid on their arm, and a CDC card with handwritten details such as when it was provided and which type of vaccine it was.

The CDC card is a tradition that goes back to the 1880s, when paper cards were first used to let students return to schools amid a smallpox outbreak.

Click here to read the article

How COVID-19 Has Changed the Healthcare Supply Chain

By Denise Odenkirk for Industry Week

Data that supports forecasting, planning and collaboration allows manufacturers to get ahead of potential shortages well ahead of a crisis.

Click here to read the article

Covid-19 Vaccines, Vulnerable To Theft, Leave Healthcare Supply Chains Scrambling For Security

By Sharon Goldman for Forbes

With reports that Covid-19 vaccines are being stolen and sold on the black market, Tom Knight, CEO of Atlanta-based inventory visibility and analytics firm Invistics, says he saw this coming back in April 2020.

Click here to read the article

Executive Briefing:

Read offline

Avoiding the supply risk from serialisation with CMOs

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Andrew Love

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Be4ward CMO serialisation integration services

Be4ward provides consulting support to Pharma companies, CMOs and their other supply chain partners, to help them implement fit for purpose, integrated and timely serialisation solutions. We have a number of products targeted specifically at helping Pharma companies plan for, and manage, their

integration programs. Our services help companies whether they are integrating one or many CMOs.

Our serialisation services targeted at CMO serialisation integration include:

Companies who have already started their CMO integration program

CMO Engagement Program Health Check

A health check style audit of an existing CMO engagement program and plan to identify gaps and risks.

Individual CMO Plan and Capability Assessment
A health check style audit of an individual CMO's implementation program/project to identify gaps and risks.

Running a CMO Engagement Program

Program, project, subject matter expert and validation support for the management and execution of a CMO engagement program.

Companies who have not yet started their CMO integration program

CMO Interface facilitation and implementation validation

Using the skills in the integration groups to focus on the issues and deliver interfaces with the least level of disruption.

CMO Engagement Program Design

Facilitating the design of a CMO engagement program with a cross functional team, including:

- Scope definition
- Activities and documentation requirements
- Program plan
- Program RACI and model CMO RACI
- Standard CMO engagement plan

Key learnings 1: Be realistic about the real flexibility that CMOs have
CMOs, like all organisations, have many constraints, both internal and external, that limit what they can practically offer. It is all too easy for Pharma companies to assume that, as they are the customer, a CMO will be able and

willing to accommodate any requirement they have. Unfortunately, in the area of serialisation at least, this is not the case at all.

Serialisation is an immature area, with new and evolving legislation and standards. Equipment and information technology (IT) solutions are also evolving and maturing rapidly. Furthermore, the whole supply base is capacity constrained as the demand for equipment, IT systems and consulting services has outgrown the limited pool of skilled resource.

Most CMOs have to deal with many different customers and, from a serialisation perspective, must implement packaging line and IT capabilities and interface them to each of their customers. It is impractical for them to do this and achieve time, cost and quality customer requirements without some compromise.

This compromise often comes by the CMOs having to define a limited operating model, within which customers must conform, in order for the CMO to be able to effectively manage the situation. In many cases, the equipment and IT solutions they are using will impose constraints on them that they have no realistic way of avoiding in the current environment.

Therefore, rather than expecting CMOs to be infinitely flexible and customer serialisation requirements focussed, Pharma companies are probably better to assume they will have to adapt to a number of different and relatively inflexible CMO serialisation models.

Key learnings 2: Be realistic about what CMOs are really going to pay for
CMOs are relatively low margin businesses when compared with most Pharma companies. Indeed, one could argue that this is due to the Pharma companies doing a good job of ensuring they only pay a reasonable price for the services they receive. Therefore, CMOs do not typically make the profit margins that would allow them to absorb the very significant costs of implementing serialisation.

We have seen a number of clients waste a lot of time and effort trying to negotiate for a CMO to absorb the cost of serialisation when, in reality, this was never going to be a practical option. CMOs may be able to fairly share the cost of serialisation between customers, but to absorb the costs is unrealistic in many cases.

Therefore, Pharma companies should budget to pick up their fair share of the CMO serialisation implementation and ongoing operation costs and negotiate with their CMOs accordingly.

Key learnings 3: Understand the CMO's decision making process
Following on from our discussion about being realistic about what CMOs are going to pay for, Pharma companies also need to understand the key decision making processes within a CMO and how this will impact their own activities.

As an example, understanding the funding approval processes within a CMO can be key to ensuring a timely serialisation implementation. How a CMO makes its funding commitment decisions and what commitments they need from their customers along the way, should shape a Pharma company's engagement plan. All too often, a project will encounter unexpected and sometimes unexplained delays because the funding and commitment processes of the Pharma company and CMO are not aligned.

Key learnings 4: Be realistic about your CMOs view of your importance to them
Pharma companies would all like to think that every CMO treats them as a critical and highly important customer. However, this is just not realistic for most Pharma : CMO relationships. Certainly, you may be in the fortunate position of being a priority customer for a small number of your CMOs, but it is unlikely to be the case for all of them.

This is particularly true if, as is sometimes the case, a CMO is in fact a Pharma company themselves. In this situation, there may be two issues playing against you as the customer:

- As a contract supply product, your supply is often low margin and low priority for the supplying Pharma company
- Pharma companies are typically not well set up, with respect to serialisation and often culturally, to service a model where they are the CMO, as this is different to a model to where they are the customer

Planning on the basis of a realistic expectation of the CMOs view of your business will help avoid unnecessary supply risks.

Key learnings 5 Use risk management to focus resource application
It is unlikely that you will have enough of the right resource to manage all CMOs in the same way and mitigate all risks entirely. Therefore, managing the portfolio of CMO integration projects using a risk based approach will give you an effective way to focus resource where it will pay the highest dividends.

Different companies will measure business risk in different ways, but the principle of applying most resource to mitigate the highest business risks is likely a sensible approach.

However, it must also be recognised that this approach comes with a downside. Such a focussing of resource will mean that some areas of the program will have a higher probability of some degree of failure. Management need to recognise this and work with their teams to ensure they understand where compromise is acceptable.

Key learnings 6: Make sure you assess each CMOs capability and capacity to deliver

Our experience suggests that, just because a CMO claims they can deliver, the Pharma company customer should not take this at face value, unless failure does not matter in the bigger scheme of supply risks.

The majority of CMOs are stretched to achieve serialisation and are relying, in a large part, on the same over stretched supplier base as everyone else.

Furthermore, CMOs, being lower margin businesses than the typical Pharma company, are run much leaner than the typical Pharma company. This typically exposes Pharma companies to delivery risk levels that may not be acceptable to them.

An assessment of any CMOs likely ability to deliver can be made to help understand this risk and actively decide if and how to mitigate it. Areas of assessment can include:

Key learnings 7: Make sure you have sufficient Plan Bs

Given the immature and evolving nature of serialisation and the over-stretched supply base, things are undoubtedly going to go wrong.

Any successful CMO implementation program is going to rely on one or more alternative solutions in order to get to the finish line successfully. Some of these alternatives will likely be tactical in nature and require subsequent projects to make them good.

A Pharma company would be well advised to plan key mitigation options ahead of time, as these may require specific capabilities being put in place ahead of time.

Furthermore, there needs to be a clear and timely decision process in place to trigger the implementation of any 'Plan B', adapt plans and redeploy resources accordingly.

Key learnings 8: Ensure you have a cross-functional team on this from day 1
There are lots of inter-dependant decisions to be made and multi-functional activities which need to be done for any single CMO implementation to be successful. This is a cross-functional activity, typically including representatives from a number of groups, including:

- External manufacturing
- Serialisation
- Key serialisation vendors
- Packaging engineering and technology
- Supply chain management and planning
- Regulatory affairs and artwork management
- Quality
- IT Technical to create/manage technical interfaces
- Computer system validation
- Procurement and legal
- Finance

Making sure that all these stakeholder groups within your organisation are engaged early, understand their role and the resource levels that will be required is key to success.

Then, for each individual CMO integration project, the identification of the cross functional teams from each organisation need to be agreed, as well as how they will effectively communicate with each other.

Key learnings 9: Don't believe that the software vendors can sort this out for you

One of the things that must be done for serialisation to be successful is the interfacing of two or more IT systems. Your serialisation system(s) must talk to each CMO's system(s) in near real time.

As part of their sales 'promise', the enterprise (Level 4/5) serialisation system vendors may lead you, or members of your team, to believe that they manage the whole CMO integration process for you. Whilst your system vendor undoubtedly plays an instrumental role in making the system interface(s) happen, the scope of any one CMO integration is far more than just connecting two IT systems. Often the interface will need additional master data to be exchanged you need to understand and agree any master data impacts.

Furthermore, even if the scope was just limited to connecting two IT systems, the decisions that go in to the underlying business processes and information passed between the systems has implications far beyond IT alone.

Key learnings 10: Standard ways of working are valuable, but only guidance for wise men

Given that there is a significant amount of repeat work involved with integrating multiple CMOs, there is no doubt that having a standard, templated model for the way in which you intend to deal with each CMO is an excellent starting point.

However, given that each company involved in this endeavour has their own set of external and internal constraints, the actual way of working with each CMO needs to be adapted to suit the particular situation. The project teams need to recognise this and tailor ways of working and plans to deliver the best compromise for all involved.

In our experience the discussions between CMO and customers need clear leadership to make sure that you have the right person leading the discussions.

Key learnings 11: Make sure that there is enough of the right resource engaged on the problem

Projects are only successful if there is enough of the right resource available at the right time. Serialisation is certainly no different.

Furthermore, because of the different organisations involved in each CMO integration and the immature and evolving nature of serialisation, it is likely that repeat activity will show some improvement in efficiency, however, perhaps not as much improvement as might otherwise be expected.

The other significant issue with serialisation over the next few years is the fact that the experienced serialisation resources and the equipment and IT system vendors will be highly stretched to meet the demand.

Key learnings 12: Make sure your internal RACI is clear

For the purposes of this discussion, by RACI we mean ensuring that everyone understands who has: Accountability, to make sure a decision happens; Responsibility for doing the work; those who must be Consulted before decisions can be taken and finally, those that must be Informed when a decision has been taken.

There have been many years of industry practice and often internal experience to agree how the typical external supply decisions are made and captured. Serialisation is an area where everyone is learning as they go along and therefore, there is no commonly understood 'playbook'.

Decisions associated with a serialisation integration will fall in to a number of areas, including:

- Relationship and contractual
- Serialisation design
- Quality and validation
- Implementation timing and coordination
- Funding

Furthermore, serialisation tends to fail in the details, as several IT systems need to be connected in near-real-time. As experience with IT probably tells you, if the details are not exactly correct, then such connections simply do not

work.

This is a new area, so sorting out the RACI for decisions in a way that ensures the overall impact of any individual decision is understood and agreed is key to success. Often the team will include two 3rd party software suppliers — the customers and the CMO — it is critical that these resources are identified in the RACI.

Key learnings 13: Make sure everyone understands how this is going to work

As with all projects, there are two principle aspects of a CMO integration that need to be worked out:

- How is the end-to-end final result going to work — the 'To-Be' design.
- How are the team going to get from where they are to the end result — the Project design.

An example of a critical area would be the integration of your quality system to those in each of your CMOs.

A small number of key individuals in any project need to understand how both aspects are going to work. All too often, we see situations where nobody understands the overall picture at a sufficient level of detail, but many members of the team can identify unresolved issues. In these cases, projects typically fail, or at best, are late and over budget.

Key learnings 14: Ensure there is a clear data and messaging model in place

Ultimately, serialisation is about maintaining an information view of what is happening in the physical [product packaging, movement and consumption] supply chain. Furthermore, this information typically needs to be shared across several locations, organisations and IT systems to work correctly.

To work at all, this information and the way it is communicated needs to be entirely consistent to the finest level of detail across the end-to-end supply chain. This is not to say that individual data items or message methods need to be exactly the same across the end-to-end supply chain, as the likes of

middleware can accommodate a degree of data and message format transformation. However, in order for this transformation to work successfully, the underlying data needs to be consistent and transformable using simple rules, across the end-to-end supply chain.

Unfortunately, whilst standards exist for a significant portion of these information and messaging requirements, several issues arise, including:

- Legislation requirements that are not all consistent across countries.
- Standards, when applicable, that do not cover the full scope of the problem.
- Standards, where they exist, that sometimes leave many options as to how specific processes and information communication can be done.
- Different equipment and IT solutions that have different constraints placed on the way in which information can be represented and communicated. This is particularly true in the relatively immature area of serialisation.

Therefore, defining an organisation's data and information communication model across their part of the end-to-end supply chain can help considerably in understanding inconsistencies and designing effective solutions in a timely manner.

Key learnings 15: Ensure there are repeatable test protocols in place
Not only are there many system connections and product implementations to perform in a typical serialisation program, but there are also many changes that will be needed along the way as well.

There are not only many systems involved, but each of these systems will typically have a number of environments through which any changes need to be propagated, e.g. development, testing and production environments.

Given the relatively immature nature of serialisation and the over-stretched nature of the supply base, the opportunities for error in coordinating all these changes is plentiful.

The use of standard test protocols can go a long way to ensure that not only new changes function correctly, but also to ensure that any changes do not have unintended effects.

Key learnings 16: Separate capability implementation from product cut-over
For many organisations, there are many individual products that need to be serialised, but a much smaller number of capabilities (e.g. packing lines, CMOs, 3PLs) that need to be serialisation enabled.

Furthermore, organisations are normally well set up for implementing packaging changes on products and recognise that this, in itself, is a relatively complicated coordination activity of many moving parts.

On the other hand, serialisation capability implementation is typically the realm of the serialisation program/project teams, with an emphasis on one-off changes to significant capabilities and establishing new organisation and systems integrations. This would typically include any changes to the ongoing pack change implementation processes in an organisation.

Once these new capabilities have been established, implementing the individual pack changes should be very much 'business as usual' for an organisation, typically managed and coordinated from the supply chain and planning teams in an organisation.

It can be very effective to divide the responsibilities for serialisation capability implementation and subsequent individual pack change serialisation cut-over to different teams. This frees the serialisation capability implementation to focus on what they should be good at, whilst leaving the individual pack change implementation activity to the existing teams in the business who best know how to do this. It can also serve to ease some of the political tensions that are often seen in serialisation programs at this organisational interface.

Key learnings 17: Treat this as a program (unless you only have one CMO)
Each specific CMO integration will be different in a number of ways, as each CMO is a unique organisation, with its own:

Governance

Organisation and people

Serialisation solutions and vendors

Quality system(s)

Contractual and finance requirements

Timelines and constraints

Culture

Therefore, each implementation is at least one project, if not several, if a phased implementation is required.

Therefore, it is sensible to treat the overall CMO integration activity as a program, ensuring that the appropriate level of program management capabilities are applied to the problem.

Furthermore, successful programs tend to be those that recognise that program management skills are distinct and different to project management skills.

Key learnings 18: Recognise and cater for ongoing change

There are many reasons in the serialisation area, why what is implemented initially will need to be changed over time. Examples of these change drivers include, but are not limited to:

- Changing legislation and standards
- Changing product portfolio
- Changing product supply chains
- Changing or evolving supply chain partner capabilities

Any serialisation program therefore needs to recognise these drivers, and have a way to understand and manage their impact and adapt accordingly.

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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Andrew R Love

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Once the translation reviews have been completed and all edits are agreed, the final translation needs to be approved.

There are two things to consider at this point; **who will approve the translation?** and **how will this approval manifest itself?**

These two aspects are probably influenced by the type of material being translated and the usual approach to document approval in your company. If the translated material is for internal use only and the impact of error is not of great significance, then the approval process will likely be relatively informal. However, when the translation is for an external audience and accuracy is paramount, for example involving pharmaceutical labelling or legal documents, then a strict and formal approval process should be considered.

Who should approve the translation?

We can expect that the person who prepared the translation and the person who reviewed it should both be approvers of the finalised document.

However, the question is should anyone else be involved as approvers? Should the project manager from your company be an approver? This may be particularly important where both the creator and reviewer of the translation are not employees of your company. You may wish to have a document being used by your company to be approved by an employee of the company.

Do you need other functional approvers to comply with any document approval rules or common practices within your company? Are there certain functions, for example quality assurance, that must approve certain types of documents? If there are, you may need to prepare approval matrices that show who should be involved in approving which documents to guide your project managers.

As well as defining who should be an approver, you also need to consider what they are approving. By nature, these documents are in a foreign language, therefore there is a potential risk that some roles, considered important as 'approvers', cannot read or understand the content in a foreign language. You therefore need to consider what it is that they would be approving. It could be that the process has been followed correctly and all outstanding issues have been addressed. It could also be to check specific items on content not affected by the translation, for example the correct use of trademarks and registration symbols. We would contest that there is little value in someone approving a document where they have no comprehension of the content. Therefore, you need to consider why someone needs to be an approver; what it is that they are expected to approve; and how they will be capable of doing this.

How is the approval performed?

The second consideration is how the approval manifests itself. Again, there may be specific processes or systems in your company that dictate what you need to follow. However if not, you need to consider the required level of formality and the need of an audit trail for the final approval.

Regarding the formality of the approval, there are probably two ends to the spectrum. On one hand, it may be appropriate to have an informal approval confirming that the translation is acceptable for use from each required

individual. This may take the form of a verbal message or email and has basically become a formal audit trail.

On the other hand, it may be required to have a formal recorded approval process that provides an audit trail of the final authorisation of the document. This could take the form of a signature block on the translation or an associated approval form, or an electronic signature on the file or within your document management system. This is obviously a more onerous requirement.

It can therefore be seen that the type of approval should be appropriate with the type of document translated. The degree of rigour and formality applied to the approval process should increase as the significance of the document and the impact of error increases.

The next blog will be the tenth and final set of tips in this series, and we will look at securely storing approved files and building translation memory; ensuring effective document management and how to start building a library of standard phrases.

Should you have any questions or feedback relating to this or any of our 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

Read it online

COUNTERING COVID-19 CRIMINALITY: BATTLING PHARMACEUTICAL CYBERCRIME

By Grant Courtney | Principal Consultant

Perhaps the most eagerly anticipated therapeutic innovation in the history of time, the first effective Covid-19 vaccine is now rolling off the production line and out to the world. Producing and successfully distributing an effective vaccine has signaled a significant step towards addressing a global

pandemic that has crashed economies, curbed freedoms, claimed close to 1.5 million lives worldwide and sickened more than 63 million. Projecting into the not-too-distant future, the fully vaccinated will be able to enjoy greater freedoms; to interact, to travel, to work and to return to some sense of normality. That the ticket to these freedoms is potentially contained in a small glass vial, makes these vials at high risk of falsification and counterfeiting by criminals seeking profit from the misfortune and fear of others.

I have written before about the importance of using established traceability standards to secure the legitimate vaccine supply chain. However, to truly and effectively protect the legitimate supply chain, we must not overlook the illegitimate one. One of the most significant contributing channels in the illegitimate pharmaceutical supply chain is cybercrime, more specifically the sale of falsified medicines online. Cyber-criminal organisations haven't lost time in exploiting the Covid-19 pandemic. If anything, they've been quick to shift towards a new area of growth and profitability, one that is driven by the fear and uncertainty that accompanies the pandemic-related morbidity and mortality. Fortunately, governments, pharmaceutical companies and trade associations have spent decades keeping pace with the ever-evolving tactics of cyber criminals.

A recent report from the National Association of Boards of Pharmacy (NABP) identified dozens of sites where falsified or bogus Covid-19 treatments are offered. Sometimes these sites were already operating and only added coronavirus-related images to profit from the pandemic. Other sites have purchased domain names including Covid-19 key words, such as 'covid', 'corona' and 'virus', drawing visits from unsuspecting or desperate users but also raising red flags.

A two-pronged offensive

As the techniques used by the sellers of illicit medicines are becoming more and more sophisticated, so too is the fight against them. There's a dual strategic attack on cybercrime at play. Firstly, an effort to educate the public about legitimate internet pharmaceutical commerce sites. This is accompanied by mechanisms to police the most popular e-commerce

platforms, such as eBay and Amazon, and secure the buy in of internet infrastructure providers in an attempt to stamp out dubious sellers.

Policing the sellers

Since the start of the pandemic, Amazon has suspended tens of thousands of sellers of illicit medicines, in collaboration with the US and European authorities. Regulatory bodies have also contributed to this online offensive. In April, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) suspended 9 domain names and social media accounts selling fake or unauthorised Covid-19 products. Since March 2020 the U.S Food and Drug Administration (FDA) has issued more than 140 warning letters to individuals and companies for unapproved or misbranded products related to the pandemic. The agency's *Operation Quack Hack* alone netted hundreds of online marketplaces alleging availability of Covid-19 preventatives, treatments and cures.

Major players in the fight against pharmaceutical cybercrime are two non-profit patient safety organisations: the European Alliance for Access to Safe Medicines (EAASM), and the Alliance for Safe Online Pharmacy in the EU (ASOP EU). These organisations have spent the last decade raising public awareness of falsified medicines, with campaigns like *Counterfeiting the Counterfeiter* and *Facts about buying fake medicines*. This last campaign ran in five countries (France, Germany, Italy, Spain and the UK) and with over 35,000 first page search results per day, it demonstrated the public interest in buying medicines online.

ASOP EU is currently trying to get traction from search engines, online marketplaces and social media platforms to integrate artificial intelligence into their platforms, to identify rogue websites and online sellers and automatically demote them in results. Placement in later pages will effectively remove them from immediate access by consumers. This has proved successful in the field of illegal streaming of videos and could likely be repurposed for pharmaceutical sales online but would require a willingness by the search, social and online marketplace companies to focus on solving the problem.

A crucial element in policing this form of cybercrime is the required buy-in and monitoring by internet infrastructure providers, such as domain

name registries and registrars. Domain name registrars sell domain names to registrants, the end-user or operator of a website. Domain name registries operate the top-level domain itself, like *dot com* and *dot pharmacy* and contract with registrars to sell domain names. ASOP EU has launched an effort to involve domain name registries and registrars in the fight to protect patient safety online. ASOP EU believes that the Digital Services Act (DSA), the EU plan to regulate digital services, should mandate that registries and registrars maintain a transparent registrant database, called the WHOIS record, for domains used for commercial purposes, with proof of identity.

For more than 25 years, WHOIS has required domain name registrants to provide correct and verifiable contact information, including name, address, phone number and email address upon registration. Combined with certain other attributes of a domain name's registration, this is collectively called WHOIS data. Authorities such as the US FDA, the UK MHRA, and trusted third-party notifiers such as LegitScript, NABP and others could use the WHOIS data to inform registries and registrars of domain names used to facilitate Covid-19 scams, illegal online sales of medicines, and illicit drugs. EU and US authorities and cybercrime experts have also weighed in on the importance of WHOIS data transparency.

Requiring domain name registration data transparency would strike a blow at the core of online falsified medical product networks by limiting their ability to operate anonymously. Most belong to organised criminal networks that have already been targeted by authorities such as the FDA and European law enforcement authorities. These rogue networks create website templates and run back-end services such as payment processing and product shipping. The website templates are then run by 'affiliate marketers' who operate them, drive traffic to the illicit websites and take a small cut of the profits. These multiple links create multiple opportunities for law enforcement to identify rogue actors within a database. The weak links in an online illicit pharmacy operation would lead to its demise.

EAASM and ASOP EU have been at the forefront of efforts to translate internet policing programmes into legislation. The scale of the problem is immense, and a huge part of the problem is the very existence of the customer base. Afterall, if the public was not there to create the demand, the supply would not be needed.

Educating the world – knowledge is power

ASOP EU and EAASM recently conducted a joint survey, which found that between 35% and 58% of citizens of the five largest EU members have bought medicines online. This tracks along with ASOP Global's recent consumer survey from July 2020 which found 35% of Americans purchasing prescription drugs online, up from 33% in 2017. Confidentiality, convenience, speed and savings were the most common reasons invoked.

Most respondents, from 36% and 85% depending on the country, weren't aware of the need for online pharmacies to display the common EU Falsified Medicines Directive logo. Encouragingly, more than 90% said they would change their online behaviour and seek out an authentic online pharmacy or go to their bricks and mortar local pharmacy after learning about the magnitude of the problem and the existence of websites selling illicit medicines. The study essentially showed a woeful lack of knowledge of these websites and few were aware of the Common Logo, which each legitimate EU online pharmacy must display. This problem exists with healthcare providers too, in that they are unequipped to effectively counsel patients on illegal online drug sellers or counterfeit medications. More than half could not distinguish a legitimate online pharmacy website from an illegitimate site.

Raising awareness of the use of the internet domain *dot pharmacy,* currently well established in North America for legitimate online pharmacies, is a further initiative to counter pharmaceutical cybercrime. The Pharmacy Verified Websites Program is operated by the National Association of Boards of Pharmacy and aims to provide a safe and legitimate source of prescription drugs and related content online. Additionally, EUrid which operates the .*EU* country code top level domain name has more than two million websites and has a memorandum of understanding with ASOP EU to examine suspicious websites monthly.

ASOP EU has proposed the use of the *dot pharmacy* top-level domain across all the Member States so in Germany it would be '*dot apotheek,*' in Spain '*dot pharmacie,*' in Italy *'dot farmacia'* and so on. Some registries have more than stepped up to the mark to 'clean' their platform of websites selling illicit medicine. As a broader intervention, the use of country-specific *dot pharmacy* domains could serve to provide individuals with a tool

to help legitimise the practice and provide consumers with a method to verify safety online.

These examples illustrate just a handful of the many organisations devoted to making the world of online pharmaceuticals a safer place. Covid-19 vaccine related cybercrime is by no means a new supply chain protection issue, yet it is evolving and although we can learn from past lessons it is important to keep pace with these developing markets. Raising awareness, education and effectively removing the customer base from this illicit trade is of significant benefit. This will be all the more effective alongside the support of and active monitoring by brand owners, manufacturers and the big ecommerce platforms and the introduction of more robust legislation, trusted site signals and enforcement. As with many issues, the Covid-19 pandemic has pulled the practice of rogue online pharmacies into the spotlight, further serving to help the global education effort. Yet it is only through the engagement of all the key stakeholders that the battle will be won.

ASOP EU Facts and Tips

The facts

- Over 35,000 websites sell illegal medicines
- 95-96% of websites selling medicines are operating illegally
- Fake medicines may have too much, too little or no active ingredients
- Fake medicines may contain poisons such as paint thinners and other deadly ingredients
- Fake medicines are often made in unsanitary and non-sterile environments

Top tips

Don’t buy from an online pharmacy that:

- Does not have a licensed pharmacist, or physical address and a telephone number that works
- Offers bulk discounts or ‘amazing’ claims and results
- Does not require a valid prescription for a prescription medicines. This tells you straight away it is operating illegally

- In Europe does not display the common logo

Useful links

Alliance for Safe Online Pharmacy https://buysaferx.pharmacy/eu/

European Alliance for Access to Safe Medicines https://eaasm.eu/en-gb/

Medicines and Healthcare products Regulatory Agency https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

National Association of Boards of Pharmacy https://nabp.pharmacy/

Counterfeiting the Counterfeiter report: https://eaasm.eu/wp-content/uploads/CtCreport2012.pdf

Facts about Fake Medicines report: https://onlinepatientsafety.org/

Read it online

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