Welcome to our final Be4ward newsletter of 2021, 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 Be4ward's recent appearance at the annual Making Pharmaceuticals live UK conference, and a look at our new Be4ward company brochure.

We share our consultants' thoughts and knowledge via our monthly blogs looking at the top 15 causes of proofreading errors and our Principal Consultant, Grant Courtney, gives his thoughts on the latest discovery of fake Covid vaccines in Iran. 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: **Legal Restructuring Post Merger and Acquisition**, looking at how to manage product and licence packaging changes in these circumstances.
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.

Wishing you a very happy holiday and prosperous New Year.

Kind regards,

The team at Be4ward

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Company News

Be4ward

Be4ward returns to live conference at Making Pharmaceuticals 2021

October saw the long-awaited return to live conferencing for a selection of our consultants at Be4ward, speaking on a selection of topics at the Making Pharmaceutical conference, postponed from April.

The Be4ward topics and speakers included:

Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities: Andrew Love **VP**

Pharmaceutical Packaging in the Digital Age:

Grant Courtney **Principal Consultant**

Serialisation in 2021 – Delivery and Challenges:
Grant Courtney **Principal Consultant**

Making Pharmaceutical Packaging that is Easy for Elderly People to Open:
Stephen Wilkins **Chief Executive- Child-Safe Packaging Group**

If you would like to receive a copy of any of these presentations, please get in touch.

Company Brochure

Be4ward

Access our new-look brochure here for more information on Be4ward and the consulting services we provide.

Company Blogs

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TOP 15 CAUSES OF PROOFREADING ERRORS - PART 3

The top 15 reasons why pharmaceutical labelling and artwork proofreading fails to identify packaging labelling and artwork errors.

Proofreading is a critical quality control step in the process of ensuring that the packaging labelling and artwork of finished pharmaceutical product is correct. Mistakes in this artwork can put patient safety at risk. Therefore, ensuring that there are adequate processes, people, facilities and tools in place to perform high quality proofreading activities is essential to patient safety. This blog series identifies a number of errors which are typically seen in the design and execution of proofreading capabilities which should be avoided to ensure a quality proofreading result. Whilst this blog is written specifically with packaging labelling and artwork proofreading in mind, many if not all the points hold true for proofreading activity of any documentation or design. In parts 1 and 2, we looked at the first 6 causes of proofreading errors. Here in part 3 we study 3 further causes.

Read it offline

Read it online

Fake COVID-19 Vaccines In Iran . . . A Timely Reminder!

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Medical Product Alert N°7/2021: Falsified COVID-19 Vaccine AstraZeneca (who.int)

Medical Product Alert N°6/2021: Falsified Pfizer-BioNTech COVID-19 Vaccine (who.int)

Why was this so timely . . . ?

Read it offline

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Executive Briefing

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Executive Briefing:
Legal Restructuring Post Merger & Acquisition
Managing Product Licence & Packaging Changes

Stephen McIndoe
Andrew Love

The integration of legal entities as the result of mergers and acquisitions, and their subsequent impact on the local registration and labelling of product, poses the newly-formed organisation with both opportunities and significant risks.

Done well, the activity will deliver a new optimal and tax-efficient legal structure, appropriately revised local product registrations and product labelling changes, without impacting the free flow of product to the customers or incurring unnecessary cost.

Done badly, the worst case can result in failure to supply, both in the short and long term, when new or revised product registrations or product label changes are not approved and available in a timely manner. Furthermore, internal costs associated with poor coordination of this activity can also be significantly higher than necessary.

This white paper discusses a managed approach to this challenge, the capabilities that will be required, and lessons from previous experience in this area.

Read the **Executive Briefing** to learn more

Read it offline

Read it online

Top News Picks

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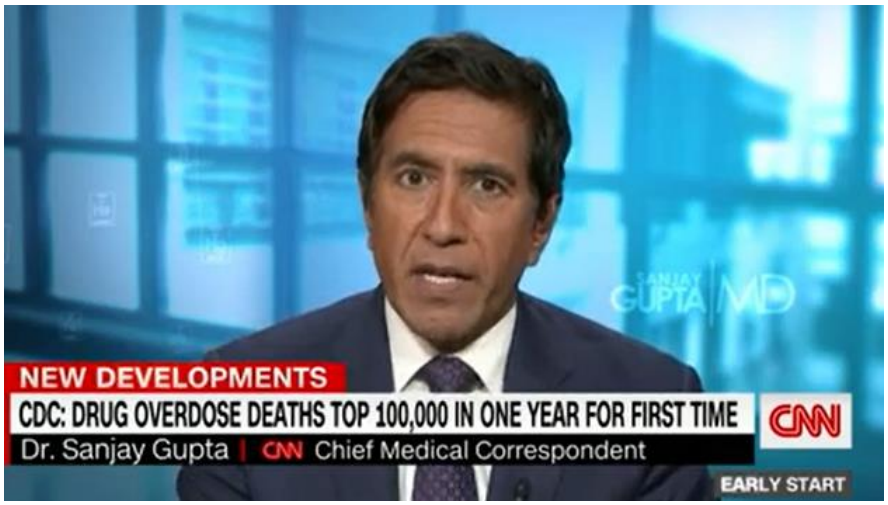

Americans are overdosing on a drug they don't know they're taking

By Zachary B. Wolf for CNN

Fueled by the coronavirus pandemic and an increase in fentanyl use, the US drug epidemic exploded while Americans were locked down.

Click here to read the article

Can the packaging industry cope with a supply chain in crisis?

By Hannah Cole for **Packaging Europe**

With the ongoing impacts of COVID-19, surging prices for energy and raw materials, and Forces Majeures destabilising the global supply chain, we spoke to Bernard Lombard from Cepi and Ron Marsh from the Polymers for Europe Alliance to find out how the packaging industry is faring.

Click here to read the article

Op takes down nearly half a million fake-peddling websites

By **Phil Taylor** for **Securing Industry**

An enforcement campaign against websites offering pirated content and counterfeit goods has resulted in almost 495,000 websites being taken down and the seizure of hundreds of thousands of fake goods.

Click here to read the article

Executive Briefing:

Ensuring Effective Translations

Stephen McIndoe
Andrew Love

Executive Summary

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Post Merger and Acquisition Integration Challenges

Mergers and acquisitions (M&A) present organisations and their staff with a very broad array of challenges which need to be dealt with in a relatively short period of time. In the run-up to an M&A, a small team is normally focussed on setting up the deal in a relatively confidential environment. They rarely have the time or opportunity to thoroughly plan the aftermath of the deal. Once the deal is agreed, the organisation often faces a huge change-management challenge as many aspects of the business need to be modified simultaneously.

One of the implications of most M&As is that the legal structure of the business needs to be changed, which in turn has an impact on both the local product registrations and the product labelling. Specifically, product registration and label changes need to be made because of:

- Changes to product license owners and numbers due to ownership transfer.
- Changes to company names due to ownership transfer.
- Changes to registered office addresses as commercial locations are rationalised.
- Changes to manufacturing locations as the supply chain is rationalised.

In parallel, there is the inevitable pressure from the commercial organisations to harmonise corporate branding.

Most regulators have strict local guidelines to follow for such changes, including:

- Levels of approval required by the regulator.
- The period of time you have to change your portfolio (the regulatory change window).
- The implications for failing to change the portfolio in this timescale.

Little harmonisation of these rules exists. Failure to comply will risk supply continuity.

In this high risk and high stress time for the new organisation, it is important that a robust plan is developed and executed which minimises this supply risk and any associated internal costs. This activity is made more challenging because it needs to coordinate activity from across and outside the organisation to be successful.

The Benefits of Doing It Right

Done well, the changes to the product registrations and labelling should be invisible to the organisation. It is an enabler to the integration, not a prerequisite or benefit. Key measures of success include:

- No supply interruption, lost sales or stock-outs
- No adverse regulatory events
- Minimal material write-off and other internal costs

Whilst challenging, with good planning, co-ordination and governance, these can all be achieved.

A Managed Approach

Successful execution of this change relies on coordinating many cross-functional and geographically disparate activities. It is further complicated because to be successful it requires the involvement and cooperation of external regulators, commercial and supply chain partners.

The high business risk, combined with the repetitive nature of much of this activity, means that establishing an appropriate level of central governance, knowledge sharing, monitoring, and corrective-action management is necessary to achieve an optimal result. The degree of central management needs to be

balanced with the need to ensure that local groups are empowered to carry out the actions that they are clearly accountable for.

The Capabilities Required

Designing and delivering such a change program requires the active and effective participation of the majority of functions within the organisation, together with a number of external partners and experts.

Many organisations have no history of significant M&A activities. It is hardly surprising therefore that they lack the necessary capabilities to achieve this change successfully. Careful consideration should be given to ensuring the right skills and experience are available for key parts of the activity, particularly the design and mobilisation of the change.

Effective Governance

Effective, timely, cross-functional (and organisational if appropriate) governance, sponsored from the top of the new organisation, is critical in achieving a number of objectives:

- Adequate resourcing of the program.
- Effective and timely decision making at the right levels in the organisation.
- Championing and ensuring real buy-in across the organisation to the decisions made.
- Effective prioritisation. Make sure you have the change capacity for the high benefit, short change window markets before allowing other integrations – these ones are the highest risk.
- Ensuring cross-functional decisions are made providing the maximum benefit to the overall organisation rather than accepting functional trade-offs.
- Effective resolution of the many issues and conflicts which will arise.

Designing and establishing an effective governance model and team(s) are critical early steps in this complex process.

These governance teams require active, pragmatic, and broadly experienced team members who will not be afraid to make decisions on behalf of their area of the business, whilst keeping them involved where necessary. Furthermore, when dealing with the rest of the organisation they need to act as key champions of the change.

Managing the Change

The nature of this sort of activity is such that it involves many parts of the organisation, in almost all locations, in a complex web of interrelated activities. Our experience suggests that it is very difficult, if not impossible, to establish simple boundaries around groups and let them design and execute their own change. Furthermore, due to the repetitive nature of many of the tasks involved, it would be sub-optimal and introduce unnecessary risk. A designed and managed program of activity needs to be established.

This is not to say that the centre has to control every detail and that the rest of the organisation simply executes the plan. Far from it, we recommend that the central design of the program should drive detailed decision making at the right level in the organisation. What is important in this process is to understand the key interactions between the decision-making and activity.

Therefore, it is almost inevitable that some form of central multi-functional program management and coordination group needs to be established. This group should be changed with the following:

- Establishing a common language for the change.
- Developing common tools and techniques to be used locally.
- Ensuring coordinated local plans are in place.

- Managing interfaces.
- Monitoring progress.
- Ensuring significant risks are identified and mitigation activity is in place.
- Facilitating the timely resolution or escalation of issues.
- Ensuring effective communication is in place with all stakeholders across the program.

The end result is well worth the apparent additional overhead and cost. You do not want to risk your supply continuity by managing through chaos.

Learning from previous experience

Our team's experience in this area has given us some key learning points:

- Only change what you really have to.
- Balance the whole cost of any individual change against the benefit of that change.
- Make sure priorities are defined and agreed at the highest level. Eighty percent of the benefits will likely be delivered from twenty percent of the markets. To minimise your supply continuity risk, ensure that your pack change capability is focussed on the markets that matter.
- At all cost, try to avoid changing manufacturing site legal entities. If you have to, try to coordinate changes with the market-driven changes.
- Rationalise the product portfolio before you change.
- Don't start an integration until you have to, and ensure that local teams can't start their integration process without central approval.
- Make sure that you have a clear single leader for the activity who reports directly to the governance team, and has both the capability to work cross-functionally and cross-regionally and the skills to lead complex multi-faceted programs.

Where to Start

Do not start integrating until you have a plan. In any country you have the control over when you start integrating, but once started you have to comply with the prescribed timelines.

Careful design of the program of activity is the only sensible place to start, together with establishment of an effective and efficient governance model.

We would welcome the opportunity to discuss how we might help you design and implement your post merger or acquisition activity.

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.

Top 15 Causes Of Proofreading Errors - part 3

The top 15 reasons why pharmaceutical labelling and artwork proofreading fails to identify packaging labelling and artwork errors.

Proofreading is a critical quality control step in the process of ensuring that the packaging labelling and artwork of finished pharmaceutical product is correct. Mistakes in this artwork can put patient safety at risk. Therefore, ensuring that there are adequate processes, people, facilities and tools in place to perform high quality proofreading activities is essential to patient safety. This blog series identifies a number of errors which are typically seen in the design and execution of proofreading capabilities which should be avoided to ensure a quality proofreading result. Whilst this blog is written specifically with packaging labelling and artwork proofreading in mind, many if not all the points hold true for proofreading activity of any documentation or design. In parts 1 and 2, we looked at the first 6 causes of proofreading errors. Here in part 3 we study 3 further causes.

Cause 7 – Not Ensuring Source Data And Documents Are Correct

The act of proofreading inevitably means verifying information from source documents or systems with the information contained in the finished document. Many artwork errors have occurred because individuals have used the wrong source data or documents.

The first example of this would be the use of personal stores of information or documents. This circumstance frequently occurs when corporate information sources are difficult to access or use and individuals resort to holding their own store of information to make their jobs more efficient. The obvious risk here for proofreading is that the source information that is referenced from the local

store is, in itself, incorrect. This may be because it has been incorrectly transposed by the individual collecting it, a situation often occurring when individuals collate their own spreadsheets of information useful to them in their day to day work.

Alternatively, the information may be drawn from a document which has subsequently changed in a later revision. Because the source document was held in a local uncontrolled store, the individual is not aware of the change to the information being checked.

Therefore, we would recommend that work instructions state clearly where source information is to be taken from in order to perform the proofreading activity effectively. It is important that anyone providing source information to the artwork process is responsible for ensuring the accuracy and currency of that information.

Cause 8 - Not proofreading all instances of an artwork

Artworks often exist in a number of different forms, each one having subtle differences. Take for example the situation where a single artwork is used to create one or more print ready files for one or more printing machines. In this case the artwork, although ostensibly the same, is actually two or more different artworks.

For reasons we discussed in 'cause 4', it is easy to assume that these different instances of the artwork are the same for all material purposes. After all, the printer’s artwork file only has some specific printer codes and markings added to it. Nothing in the artwork that will appear to the patient is changed. By now you will have realised that, even if the intent is not to change the artwork when creating these instances, it can happen by mistake.

Unless there is a validated method that prevents material changes to the artwork occurring, we would recommend that each time any iteration of the artwork is created that it is proofread appropriately.

Cause 9 - Not using checklist to ensure everything is being done

Proofreading requires a great deal of concentration and can often take a considerable period of time. For example, it is not uncommon for a manual proofread of a long multi-language leaflet to take a day to complete. Furthermore, because of the nature of the task, proofreaders need to take frequent breaks to maintain adequate levels of concentration whilst proofreading.

Given that proofreading requires people to repeat many detailed tasks over a long period of time, it is not surprising that it is easy to forget to do certain tasks unless there is some aid memoir built into the process.

Checklists provide an excellent way to remind people of the detailed tasks they need to perform during each and every proofread and give them a convenient way to record their progress. Completed checklists can also form a useful part of the audit trail for a change at critical verification and approval points.

In our next blog we will look at three further causes of proofreading errors. In the meantime, if you have any questions, thoughts or feedback to share with us or indeed if we can help you with your proofreading matters, please get in touch on enquiries@be4ward.com

Read it online

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Today I read about falsified COVID-19 vaccines being identified in the Islamic Republic of Iran. This demonstrates that the fight against fake medicines is ongoing and serves as a timely reminder about the risks being faced by patients.

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Why was this so timely . . . ?

Only yesterday I had the privilege to join a panel at the GS1 Healthcare 3rd Online Summit. The session focused on the progress being made in Africa, on the journey towards Healthcare Supply Chain Traceability.

The session chaired by Tom Woods, Global Steering Committee for Quality Assurance - World Bank, highlighted the progress being made in countries such as Nigeria, Ethiopia, Zambia, and Rwanda.

Also included was a presentation of the Verification and Traceability Initiative, which is supporting countries to reduce the urgent risk of falsified and diverted health products. Initially focused on COVID-19 vaccines, the initiative has a vision of working towards national traceability of all vaccines, medicines, and health products.

UNICEF and its partners (USAID, Gavi, The Global Fund, The World Bank, Bill & Melinda Gates foundation) provided an overview of the repository, currently

being set up, which will allow the verification of COVID-19 vaccines, using GS1 standards.

Whilst systems alone will not fully address the risks, when combined with other interventions, such as destroying used vials and packaging after use, we can make a difference in the fight against fake healthcare products.

One of my takeaway thoughts, having participated in the Summit, is that we are now at the start of the next wave of countries which are embarking on their journey towards Healthcare traceability. There is also a tremendous drive by these countries to deliver the benefits which we have seen in places such as Argentina, Turkey, and the European Union. We must support these countries and use the knowledge and experience gained over the past ten years of traceability deployment to help them be successful.

There is no doubt that we are going to see more Lower Middle Income Countries (LMICs) adopting GS1 standards to increase supply chain visibility and secure the supply chain. We must all do our part to support these countries on their journey towards traceability, to ensure we protect every patient from fakes.

Grant Courtney

Principal Consultant - Be4ward

Read it online

Trusted Healthcare Experts
Transforming Supply Chains

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