IQPC Pharmaceutical Packaging and Labelling Summit
18 – 20 June, Zurich

I had the opportunity to attend, chair and present at the IQPC Pharmaceutical Packaging and Labelling Summit in Zurich on 18 – 20 June. Many thanks to Katherine Gordon and the team at IQPC for organising the event.

I presented a mini-workshop on *How to Identify the Steps to Provide a Comprehensive Artwork, Labelling & Packaging Service*. In the workshop I explored the impact of portfolio growth and complexity on artwork, packaging and labelling teams. I focused on what capabilities you might introduce to meet the challenges of growing product portfolios. I also looked at how to engage your organisation to make necessary enhancements compelling. Finally, I explored how to ensure you deliver successful outcomes.

I also hosted an interactive round table discussion, *Global Regulatory Deep Dive – Identifying Similarities and Differences Across Key Market Requirements*. I focused on analysing the global regulatory landscape – how black market trade and product counterfeiting threatens the supply of pharmaceuticals across borders. I also looked at how to ensure market compliance by identifying key international areas of regulatory similarity to exploit and differences to prepare for ISO 21296 – looking towards the new international standard on Tamper Verification techniques.

Other presentations from the event included:

GS1 Standards – A Toolkit for Fighting Against Pharmaceutical Counterfeiting
Tania Snioch, Director Healthcare, GS1 Global Office

Tania introduced the role of GS1 and how GS1 standards underpin serialisation and traceability. Tania explained how GS1 works with partner organisations through the Joint Initiative Council.

Tania also discussed the impact of counterfeit drugs in developing countries. Tania also highlighted the benefits of standardisation to hospitals and their supply chains. Finally, Tania outlined the regulatory requirements for serialisation and traceability across a number of countries that are legislating solutions.

Let's Dream Big! Clearly and Quickly Connect with Patients and Consumers Through Packaging and Labelling Artwork

Simon Cavanagh, Account Executive Brand Solutions, and Steven Brookes, Pre-Sales Solution Architect Brand Solutions, Esko

Simon and Steven talked about the digitalisation of packaging tools and packaging design, and how this will change the approach to packaging design in the future. Simon and Steven also gave an overview of Esko's tools, the enhancements that Esko have been working on, and how they address the growing challenges brought on by digitalisation.

Solutions to Optimise your End-to-End Artwork Process

Suzanne Ivory, Global Quality Director, Perigord

Suzanne talked about how artwork fits into the overall end-to-end labelling process. Suzanne discussed key drivers for change that are impacting labelling and artwork including product proliferation, data security and an increased focus on pharmacovigilance. Suzanne distilled this down to the key challenges to artwork and the solutions required to meet them. These included the need for a quality management system, an artwork management system and carefully selected long-term partners.

Anti-Counterfeiting Requirements with a Focus on Non-EU Areas

Horst Kastrup, Senior Regulatory Advisor, MEDA Pharma (retired)

Horst presented on anti-counterfeiting requirements, particularly outside of the EU. Horst highlighted the magnitude of counterfeit products in low to medium income countries, particularly antimalarials, with estimates of 1 million deaths per year due to counterfeit products.

Horst discussed several case studies across a number of products and countries. Horst also outlined the various regulatory requirements that have been introduced to address this.

Implementing Child Resistant Packaging Without the Tantrum

Stephen Wilkins, Chairman, Child-Safe Packaging Group

Stephen presented on the requirements for child resistant packaging and the background reasons for these requirements. Stephen provided an overview of the various regulations and standards. Stephen showed a number of failure modes and some examples of good practice.

Stephen also discussed the impact of packaging design on the elderly, which can be detrimentally impacted by child resistant features.

Purchasing for Patient Safety – Payer's Influence on Assessment of Packaging & Labelling for UK NHS Hospital Formularies

Omar Ali, Formulary Development Pharmacist, QIPP Advisor Payer Network and Former Formulary Advisor, UK National Health Service (NHS)

Omar's presentation covered the role of packaging in patient safety. Omar talked about the environment of medication errors and the impact on patients and healthcare professionals. Omar showed the impact of similar product names and discussed potential systems solutions e.g. electronic prescribing tools.

Omar then looked at labelling issues and what was needed to resolve them. Referring to the NPSA guide to packaging design, he showed how layout and colour can be used to help highlight specific product issues.

Overview of the FMD Challenges and Opportunities for Hospital Pharmacies

Robert Moss, Board Member & Director of Professional Development, European Association of Hospital Pharmacists

Robert discussed the implications of FMD on hospital pharmacies. Robert looked at the hospital supply chain and the issue of when the product should be authenticated within the hospital. This is a complex issue for many hospitals where they are integrated with other healthcare facilities.

Robert then discussed the other issues presented by FMD on hospital pharmacies. This included the impact on pharmacist capacity and workload, processes for product rejection and return, and impacts on cold chain product.

BfArM Pharmacovigilance Inspection – Case study from a labelling point of view

Hannah Hähl, Regulatory Affairs Manager (Labelling), Grunenthal

Hannah presented on the learnings and improvements made to Grunenthal's labelling process following inspection observations. Hannah gave an overview of the inspection process and activities. Hannah then discussed the need for more end-to-end oversight of safety variations and the introduction of a tracking tool and other process improvements they have undertaken. Hannah highlighted that regulators are increasingly looking for end-to-end oversight that safety changes are implemented in a timely manner, but that inside a company, implementation can mean different things.

Case Study – Improving Artwork Process Efficiency on a Global Scale

Russell Collins, Director, Packaging Strategy and Global Labelling Business Process, AstraZeneca and Paul Goldberg, Vice President of Product Strategy, Loftware

Russell and Paul presented on the improvements that AstraZeneca have been undertaking and the implementation of Loftware's artwork management system. Paul gave an overview of Loftware, the acquisition of Gap Systems and how their product offering will evolve. Russell explained AstraZeneca's process maturity development model and how their capability improvements have been prioritised.

They are now at the stage of considering how the labelling and artwork process will be seamlessly integrated into the overall company process architecture.

Russell showed how the improvements they are making are aligned to the company's goals and the benefits these improvements will deliver. Russell emphasised the need to focus on improvements that clearly support business requirements.

The Trials and Tribulations of a Labelling Professional

Keith Howard, Former Senior Labelling Manager, Vertex Pharmaceuticals

Keith discussed the issues faced by Regulatory and Labelling professionals. Keith walked through the life of a typical change, highlighting the issues that can arise in execution. This showed the amount of variability that can arise in the process due to different problems that can occur. Keith also emphasised the need for collaboration across and outside of the company. Regardless of the application of artwork management systems, there are still a high degree of people involved and many issues arise due to differences in opinion. Someone needs to be accountable to resolve these issues and ensure changes are delivered on time.

Increasing therapy adherence through packaging: Designing packaging that improves patient's lives

Ger Standhardt, Executive Director, HCPC Europe

Ger presented on how packaging can improve the life of patients. Ger explained the remit of HCPC Europe and the purpose of packaging. Using examples of HCPC Europe Columbus award winners, he highlighted features on packaging that improve patient adherence. These include; calendarisation, portability and discreteness, child resistance, ergonomics and provision of usage information.

How to Prepare For Delivery Of The FMD On Time And Final Considerations To Be Made

Johan Verhaeghe, National Policy Liaison, Medicines for Europe

Johan discussed the FMD regulation deployment. Johan outlined; the FMD regulations, explained the European Stakeholder model, the European Hub and national systems, and the roles of the different participants. Johan then explained that deadlines are imminent and there is still much work to do in many organisations. Country preparations are progressing but there is a concern that some may be late.

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

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