

Thoughts from the Supply Chain

The last 10 years have seen a host of developments, trends and opportunities that have moulded the pharmaceutical supply chain into what it is today. *PMPS* asks company leaders in key sectors to reflect on the past decade and to suggest what they think the future holds

PMPS: What has been the most significant event in your sector of the pharmaceutical industry over the last 10 years?

Tim Clarke, CEO of Healthcare and Technology at packaging design company Burgopak: The expansion of opportunities in both eastern Europe and the BRIC countries, as well as the increasing presence of the generics market. These have created a more diverse need for packaging solutions.

Joe Ringwood, COO of packaging optimisation company Systech International: In-line printing of variable information utilising barcodes and requiring verification. Examples include Italian Bollini, Belgian Vignette, French CIP 13 and Turkish serialisation requirements. In general, the enhanced use of coding information packaging has also had a significant effect.

Frans Maas, Vice President of Sales and Marketing, GEA Pharma Systems: After the global economic crisis, the biggest milestone has been the end of the 'blockbuster' model combined with the recent mergers and acquisitions activity in the sector.

Ameet Sareen, Manager of Cargo Product Development, Air Canada Cargo: The strengthening of international regulations has led to the development of time and temperature-sensitive solutions.

Ashley Goldie, Sales and Marketing Director at artwork management solutions specialists Kallik:



Ashley Goldie, Kallik

Risk has become an increasing issue. The FDA has stepped up their regulations and companies have lost millions in recalls. However, that sum pales into insignificance compared to the total cost to a brand and the damage to consumer confidence. Meeting the correct legal and mandatory data requirements on product packaging is critical for avoiding product recalls. Pharmaceutical and healthcare companies are realising that they need to tighten up their supply chain quality and internal processes in order to decrease the risks and repercussions of these recalls.

PMPS: What piece of legislation has had the biggest effect in recent history?

JR: The regional legislations that led to the in-line printing of valuable information.

FM: FDA guidelines on process analytical technology and quality-by-design have had a huge impact.

AS: IATA Chapter 17 governing the transportation of pharmaceuticals.

AG: The Food, Drugs and Cosmetic Act of 1938, which included a section on the importation of drugs and addressed the labelling of prescriptions in the pharmacy. The two sections of this new law that refer to medicines are the best known. The first is the definition of a new drug, and the second is Section 505 – which established the

requirement for manufacturers to apply for FDA authorisation.

PMPS: In what way has the industry changed in the last 10 years?

TC: Packaging is now part of a patient's interaction with their medication. Packaging has transformed from what was a necessary evil, to a constructive part of the medication process.

JR: Globalisation versus regionalisation. Driven by the global economy and company merger activity, there is a greater need to run more brands/products on the same lines. In addition, there will be significantly fewer product-specific lines. Furthermore, we will see a drive towards greater efficiency of the packaging line and the ability to measure it, as a result of greater use of automation to drive efficiency and cost containment. The increased use of automation has resulted in a greater number of packaging lines on networks in an effort to continue to drive efficiency.

FM: We have seen a rapid and irreversible regional shift in the majority of pharmaceutical investments towards E7 and N11 countries.



Franz Maas, GEA Pharma Systems

AS: International regulations governing the production and transportation of pharmaceuticals have been strengthened. All participants in the



cool chain process realise the role to be played in maintaining the integrity of the pharmaceutical shipment and airline standard operating procedures are also much more defined, with major emphasis placed on training and communication.

AG: Compared to 10 years ago, packaging requirements in the sector have become particularly complex and increasingly difficult to control. Compliance errors can expose businesses to potential fines for not following regulations and, in this case, non-compliance can lead to issues with health, safety and the environment.

The increasing complexity of global supply chains has also led to a need for better quality and improved management of product data in the industry. A host of small disparate databases each containing local product data have contributed to enormous data inaccuracies and inconsistencies which are impacting on profits and downgrading on-shelf availability. Improved data management means that if legal requirements or market conditions change, companies can make rapid changes at short notice, ensuring ongoing compliance to changing laws and regulations.

PMPS: What do you predict will be the big developments over the next few years?

TC: Compliance-focused solutions and the use of sophisticated technology for packaging.

JR: Broad adoption of serialisation initiatives to provide track and trace and/or authentication to yield a higher level of patient safety and a reduction in parallel trade. Full integration of item level serialisation with



Tim Clarke, Burgopak

aggregation will take place as this adoption evolves.

FM: The implementation of continuous technologies in pharma secondary will be a major step. Also, productivity and sustainability will be real business themes for new investments.

AS: Radio frequency identification, e-freight, and further emphasis on the handling of pharmaceutical shipments.

AG: XML format submissions are already mandatory in the US and it is expected that the EMA will also make it mandatory for all regulatory approvals, replacing either paper or Microsoft Word documents. However, promoting these from a database-driven submission solution, rather than a document centric one, will offer pharmaceutical companies amazing consistency of content across the vast and diverse array of communication channels.

PMPS: Where do you think the industry will be in 10 years' time?

TC: In terms of the packaging industry, can anyone predict what will happen in two to five years? With the movement of pharmaceutical medical technology, the one thing that is certain is that every year the demands and solutions required will be different from a medication and packaging perspective. The use of personalised medication and packaging for individual needs using biometric and DNA know-how, for example, is no longer an issue of how, but more a matter of when.



Joe Ringwood, Systech International

JR: Patient-specific packaging will be the norm. Each item/unit on the packaging line will have more identity (personality), with a history of where it came from, where it has been, when it arrived and departed each destination,

and where it is going, all the way back to the raw material suppliers. The ability to go beyond 'just' traceability of the product will be seen throughout the supply chain.

FM: The CMO industry will account for 50 per cent of global pharma production. Also, biotech will account for 50 per cent of global value and biosimilars will be the next big 'generic'.

AS: I expect the industry will be far more automated. Handling processes will continue to evolve and international regulatory bodies will strengthen their positions. Emerging markets like India and China will attract a lot of attention and will reinforce their activity in the pharmaceutical industry segment. In addition, the airline industry will be expected to innovate and maintain transportation costs.

AG: Pharmaceutical companies will be taking database driven XML licence submission data directly to labelling, packaging and patient information artwork – both printed and online – without the requirement for human intervention. Technology will provide pharmaceutical companies with functionality that will not only support the XML-based product approval process, but also enable the generation of labelling and packaging artworks directly from the licence submissions. These solutions will improve communication efficiencies significantly and fully support the effective management of the numerous communication channels, multiplied by the vast number of languages required throughout the new emerging markets.



Ameet Sareen, Air Canada Cargo