why does packaging labelling and artwork matter?

Packaging labelling and artwork is an often forgotten back room process in most pharmaceutical companies, but the changing business environment has brought issues from this capability to the fore.

Pharmaceutical and other healthcare companies are facing one of the most difficult periods in their history. Current products are rapidly going off patent leaving significant revenue challenges. At the same time, weak product pipelines are failing to fill the gap.

Furthermore, global markets are changing rapidly. Traditional markets are stagnating and new markets are evolving at a rapid pace. Everywhere, key healthcare purchasers are putting increasing pressure on drug prices.

In response to these significant challenges, pharmaceutical companies are looking to make the most out of their current assets. This often manifests itself in a drive to launch as many product variants in as many markets as possible. For many pharmaceutical companies, this represents a significant change in strategy.

The rapid growth in the number of drugs coming off patent, together with the increasing pressure on price from the major purchasers, has led to a huge opportunity and growth for generic pharmaceutical companies. For them, the challenges are very similar to the pharmaceutical companies, namely to market as many product variants in as many markets as quickly as possible.

In today's world, all drug companies have an increasing need to develop and maintain an excellent reputation with a diverse group of stakeholders. Pharmaceutical companies are looking to develop and maintain trust with governments and purchasing groups in order to help maintain the product prices necessary to support their significant drug development spending. The increasing competition amongst generic companies means that they each need to develop and sustain their reputation in order to win business and maintain their production licences.

Maintaining this reputation whilst rapidly growing the number of products is particularly challenging when one considers that the largest single cause of product recall is due to packaging errors. Recognising this, regulators around the world are focusing on driving improvement in all business capabilities associated with the management of packaging design and manufacture.

When launching product variants in new markets, much if not all of the physical packaging design is already established. The text and graphics, or artwork as it is known, that is placed on these physical components is what changes every time. It is this artwork design and maintenance capability that becomes critical to achieving and maintaining the objectives of both pharmaceutical and generic drug companies.

For a large global pharmaceutical company, developing artwork for tens of thousands of products is typically a process involving thousands of people, in over a hundred countries, from tens of different organisations. To orchestrate all of this activity, the right combination of business processes, organisation design, information technology, facilities and suppliers has to be managed.

For smaller organisations, whilst the scale of the problem may be reduced, all of the same challenges have to be met.

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The consequences of artwork errors

If packaging and labelling recalls are frequent and often attributable to artwork error, how do these errors occur and how do they affect the various stakeholders impacted?

What is an artwork error?

Artwork errors can be categorised into four groups for the purposes of discussion.

- ***Gross errors***
  Where significant information is omitted from an artwork. An example would be completely missing the need to change a piece of artwork in response to a new regulatory requirement.
- ***Context and meaning errors***
  Where information is presented in an ambiguous or incorrect way on the artwork. An example of this might be the inappropriate use of hyphenation causing ambiguous or incorrect meaning.
- ***Content errors***
  Where there are errors and omissions in the detailed content of the artwork. An example of this would be incorrect symbols being used in the artwork.
- ***Technical errors***
  Where there are errors or omissions in the technical aspects of the artwork. An example of this would be the wrong specification of barcode being used in an artwork.

The implications of an artwork error

The implications of an artwork error can be as far-reaching and serious as any other error with the supplied product. Artwork text and graphics describe the product and provide information and instruction for its safe and effective use.

Impact on patients

The bond between the patient and their medicine is deep-rooted. Patients trust that the product will make them better and expect that it has been developed, manufactured and supplied to the highest quality and ethical standards. Errors in the information provided with the product are significant and can be life-threatening. We are sure that you will agree that this risk to the patient's well-being is not acceptable and their confidence in the treatments they are taking must be maintained. Trust is easily lost and almost impossible to recover.

Impact on prescribers

All prescribers (whether doctors, pharmacists, nurses or other healthcare professionals) are busy people with a clear mission – to make the patients they treat better. They expect that the products and information they are provided with are fit for purpose, error-free and safe to use. They don't want to administer products that will make their patients sicker. Rectifying the patient issues created by artwork errors is a burden they neither want nor welcome. Furthermore, the remedial action following an incident diverts their limited resources away from their core purpose

These healthcare professionals are often the final decision-makers when it comes to selecting the product that is prescribed or used in the future. Hence, any lack of confidence that they may have in a particular product, brand or company can have a direct impact on the products that get used.

Impact on regulators

The remit of the pharmaceutical regulators, amongst other things, is to set and enforce the standards by which the industry must operate to ensure patient safety. They have the authority to allow or block product use and the power to take punitive action against companies who they see fail to meet expected standards. The regulatory environment is becoming ever more complex and stringent and there is less and less tolerance for artwork error. Moreover, as we have already observed, the information age means that an incident in any country has visibility to all regulators worldwide.

It is, therefore, understandable that regulators expect companies to be continually striving to eliminate artwork errors, and take appropriate actions to reinforce that view.

Impact on pharmaceutical company staff

Two groups of pharmaceutical company staff are typically impacted by an artwork error: the team managing the recall and the operations teams who support the artwork process in which the error occurred.

The team managing the recall need to focus on the immediate and urgent tasks related to identifying the impacted product, withdrawing it from the supply-chain and

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reinstating adequate supply as quickly as possible. Whilst challenging, this work is more often than not very motivating for those involved as a great deal of satisfaction can be derived from solving the immediate and significant recall problem.

The impact on the staff involved in the operation of the artwork process is somewhat different. Not only are they likely to be involved in the rectification activity, they will be heavily involved in the incident enquiry and corrective and preventative actions. Furthermore, there are the undoubted performance and morale issues that will likely need to be addressed.

Impact on the company

The impact on the company can be significant. The patient safety implications are counter to any pharmaceutical company's core values. This is compounded by the sales, reputation and sanction impacts, through unfavourable publicity, loss of customer confidence, possible loss of license and increased regulatory scrutiny and action. As we discussed earlier, in today's business environment, these impacts are potentially significant to the success of the company.

The cost impacts of these errors are also substantial. There are the immediate tangible costs of recall, product write-off, repacking and market re-supply. However, these can be overshadowed by the less tangible follow-on costs occurring through loss of sales and market share, customer reimbursement and litigation. In the extreme, these not only impact the bottom line, but can directly influence the company's share price.

The benefits of getting it right

Achieving excellence in this area can help deliver many significant strategic benefits.

- Increased patient safety.
- Improved regulatory compliance.
- Increased sales.
- Improved profit margin.
- Improved reputation.
- Reduced cost and valuable resource absorption