Labelling and its Role in Pharmaceutical Packaging

The ever-increasing legislative demands for patient information on pharmaceutical labelling often poses a packaging challenge to manufacturers and brand-owners. Patient compliance is also a major issue for the industry. Poorly worded, unclear or confusingly presented user instructions can lead to ineffective patient compliance, adverse reactions, side-effects, or at worst fatality. Pharmaceutical labelling goes far beyond functional requirements and fulfilling legal obligations.

Millions of dollars are spent each year on developing drugs that are safe for human consumption and that provide effective patient treatment. Yet an estimated 31% of prescriptions that are issued do not get collected, and 40% of those prescriptions will not be taken as directed. The consequences are severe and statistics suggest that the annual cost of non-adherence to the US healthcare system is approximately $US 100 billion, including a staggering 125,000 hospitalisations each year.

With these figures in mind, there is an even greater responsibility on manufacturers to ensure that drug usage information is presented to the patient in a manner that is easy to understand and easy to refer to, not just when the drug is first used, but throughout the course. Fortunately, manufacturers are becoming increasingly aware of the importance of labelling on healthcare products in relation to the success rate of a drug. On-pack information speaks directly to the patient, can help to improve user-appeal, and most importantly can have a direct effect on patient outcomes.

Labelling is an integral part of the patients’ treatment.

At a minimum, outside of legislative requirements, for the drug to be effective product labelling must perform the following functions:

- Communication of the brand and type of drug enclosed within the packaging.
- Communication of the strength of product, quantity and for whom it is suitable.
- User instructions, indications, contra-indications and side-effects.

However, the self-adhesive label can be used as a powerful tool that goes far beyond the realms of functionality and there is greater scope than ever before for further development.

Labelling is a Crucial Method of Communication with the Patient

Whilst strict guidelines are in place to ensure the pharmacist provides the patient with the correct strength and quantity of a prescribed drug, it is extremely difficult under most circumstances to ensure that the patient himself adheres to the prescribed course, without which there is no guarantee of the patient outcome.

There can be countless reasons for a patient to stop following the guidelines during a course of medication. Most commonly, a patient will feel better towards the end of a course of medication and therefore no longer think it is necessary to continue. For this reason alone, it is imperative that the guidelines within the labelling...
make absolutely clear why a course of medicine must be completed.

When deciding upon the design layout of the packaging, consideration must also be given to allow space for the dispensing pharmacist’s own label. Often, the pharmacist has no other option than to place his label over existing product labelling and there is a fear that this may obscure important pre-printed data. Once the product leaves the pharmacy, the only form of communication the manufacturer has with the patient is via the packaging.

Manufacturers need packaging solutions to deliver cost-effective solutions that satisfy the needs of the industry and consumers:

When it comes to designing primary packaging, labelling, informational leaflets, outer packaging and bulk packaging, every element must be taken into account to ensure the packaging line runs efficiently. The fewer packaging elements are involved, the fewer operations there are to go wrong on the packaging line and the less inventory there is to control and reconcile. Combining the primary label and the informational leaflet into a single leaflet-label is one solution.

Often there is limited space available to carry all the necessary information. However, compromising the content should not be considered an option. Reducing type size can result in the information being unreadable and may discourage the patient from following guidelines, and this may even contravene legislation. Clearly laid out, easy-to-follow user instruction reduces the need for mid- or post-treatment consultation with a medical professional or pharmacist, and is more likely to result in a positive outcome. In the case of over-the-counter products this may also increase the likelihood of a referral or even repeat purchase, thus having a direct effect on future revenues.

Commonly a loose leaflet inserted into a carton is used to fulfil this role, but care must be taken to ensure the user instructions are not instantly discarded by the patient. Alternative options such as multi-page labels are becoming increasingly popular. These may include up to 100 pages of additional information within the confines of the adhesive label. This has the added advantage of ensuring the patient information is secured firmly to the product or host-container, making it readily available throughout the entire course.

Research has shown that multi-page self-adhesive leaflet labels, attached directly to the primary packaging, are generally more likely to be read than a loose leaflet inserted into a carton. More importantly though, they are significantly more likely to be retained by the patient throughout the course of treatment.

User-friendly Product Information

The way in which the packaging is worded and designed can also have a direct effect on the patient outcome. When providing patient information, the manufacturer must take a number of factors into account to ensure everything is clearly presented within the label and packaging.

Literacy and education levels vary around the globe. Children are often dependent upon their parent to administer drugs, but a safe dosage for an adult could be dangerously high for a child. Some patients, particularly elderly ones, may have poor eyesight or find it difficult to remember when and how to take their medication, meaning they have to refer to informational leaflets repeatedly. Often, patients who are taking several long-term courses of medication at once transcribe basic dosage information onto easy to refer to handwritten reminders. Not only does this suggest that the original information was poorly presented, but it also introduces the possibility for transcription errors and leaves the patient vulnerable should an update to the on-pack information go unnoticed. These are all factors that should be considered when designing labelling.

Technical jargon and medical terms that are not commonly understood outside of the industry should be avoided. Whilst the manufacturer cannot be directly responsible for each and every patient, good labelling can improve not just the aesthetic appearance, but also make information easier to follow, thus having a direct effect on patient outcomes.

Braille printed labels for the blind and visually impaired are now obligatory within the European Union since October 2010 (Article 56(a) of Council Directive 2001/83/EC). The law states that the name of the medicine along with the appropriate strength must be displayed on all new EU registrations on the label (this includes pharmaceutical products which were launched prior to October 2005). Whilst this is familiar ground for carton manufacturers who
are used to embossing technology, most label printers have taken a little time to catch up. Fortunately, a variety of printing techniques have now been developed to produce high-quality, durable Braille dots directly onto various self-adhesive label substrates, laminates and multi-page leaflet labels. Some of these techniques now surpass traditional embossing methods.

Variable Manufacturer On-pack Data
Besides the necessary user instruction and guidelines, the label must also include a host of manufacture-specific information. This information is most commonly printed at the time of manufacture either prior to, during or immediately after the label application process. Lot numbers, batch codes and expiry dates must all be included to ensure complete traceability.

A variety of self-adhesive label material options are available which allow for high-quality alpha-numeric information to be printed onto the substrate using various printing methods, including thermal transfer, laser ablation and, most commonly, inkjet. Special consideration is needed to ensure such data is durable and cannot be rubbed off, even if products are packed tightly together when shipped.

Digital technology means there is now scope to print a range of variable data directly onto labelling and packing to ensure traceability and authentication and to allow for late-stage customisation of product labelling. The demand for this will undoubtedly grow in future and is already being seen on 2D barcodes and variable print code. Such methods of ‘E-pedigree’ printing will allow for even greater control of the whereabouts of products within the supply chain.

Clinical Trial Labelling
Taking this one step further is the role of the label on clinical trial products. The average cost of a clinical trial is around $800m, so it is crucial that every element of the test runs smoothly and the trial is at no point compromised. For printing companies this is probably one of the most challenging sectors to serve, as the trial must often run within a specific time-frame.

Commonly, trial participants are widely spread geographically and therefore labelling is required in more than one language, increasing the demand for yet more copy space. Also, there must be total confidence that printed information stays with the drug throughout. Again, leaflet-labels are increasingly being used to meet these dual challenges. Quality and packaging consistency must be at an even higher level than normal, making clinical trial printing a specialist discipline. A minor printing defect on the label such as a fleck or hickey can potentially lead the medical practitioner involved to falsely believe that they are administering the placebo or the real drug, and this could unintentionally cause them to skew results.

There is a range of labelling features and options that may be used to assist both the medic and the patient during a clinical trial. Unprinted portions for over-coding can allow additional information to be added to the label and late-stage customisation. Detachable portions may be included on the label for pre-printed or handwritten information that can be added to patient notes for reference at a later date.

Packaging Security and Integrity
Brand protection is a growing concern in all industries, and nowhere more so than in the pharmaceutical sector. According to CHP Packer International, counterfeit medicines cost the global economy an estimated $1,000bn annually. They not only undermine trust and integrity in brands, but can cause illness or even fatalities amongst the unsuspecting public. Even the rumour of a counterfeiting issue can devastate the value of a brand overnight.

Advancements in label printing technology are playing an increasingly important role in combating the counterfeiters. Holograms and tamper-evident strips provide overt identification on products. This is particularly useful where over-the-counter medicines are concerned.

Additionally, a wide range of covert options are now available, especially for high-value drugs. Hidden messages, images and even unique codes may be printed directly onto label substrates for quick identification within the supply chain. In fact, technology advancements mean that the manufacturer is now able to encrypt artwork with their own integrity marks and commission the printed labels without the printer even being aware of this information.

Clearly there is a cost attached to such advanced technology, and this does not suit all product applications. Manufacturers need to be mindful of the public’s growing awareness of counterfeiting issues, and the added value that overt anti-counterfeiting features can bring, but must also differentiate between adding value and simply adding cost.

Final Thoughts:
Given the huge cost of developing, testing and launching a new drug, it would be a false economy to use cheaper and potentially less effective packaging if doing so risks compromising patient compliance and therefore the effectiveness of the drug.

There is undoubtedly more scope for improved labelling and packaging than ever before, even within markets that are not so heavily led by legislation. The growing realisation is that a drug is only as good as the usage information conveyed to the patient. Manufacturers no longer treat packaging as an ‘afterthought’ and recognise the need for clearly-presented, easy-to-follow packaging that is conducive to positive patient outcomes.