



Is a label enough?

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Nostrapharmus ponders over whether a label will be enough, or if the education of the populous in how to use drugs will become a key marketing activity by 2020. Do Pharma companies owe more to their ultimate customers?

There are many drivers for an improvement in the quality of drug usage information provided by Pharma companies:

- The pressure of healthcare cost reductions is driving down the time that doctors have to consult with their patients. Inevitably the time available will tend to be spent on making the best possible diagnosis and less will be available for instruction on how to use the prescribed drug.
- These same overall cost pressures, together with an objective to simplify aspects of regulation in the EU, are creating an environment which is pushing for an increase in the patient's ability to self-medicate. This is exemplified by the recent legislation enabling products to be switched from POM (Prescription Only Medicine) to P ('available in' Pharmacy) status across all EU member states simultaneously. A key foundation for these switches is the establishment of rigorous risk management approaches, principally targeted towards better education of the patient on the appropriate usage of the product.
- The need to assess safety risk management needs of new Pharma products, has led to an increase in formal commitments to the management of risk. Again, this is often achieved through training in drug use and has led to an increase in the development of educational programmes for both physicians and patients. This legislation has led to a huge increase in the development of medication guides in the US, similar to the EU patient information leaflet, the sole aim of which is to provide more information on appropriate drug use.

Coupled with the need for improvement in the quality of drug usage information, is also the need for greater education in drug use. So, what tools are available now to deliver this? The drug label is clearly the central foundation for any attempt to educate healthcare professionals and patients about the drugs they need.

If you are looking for a simple, clear and globally consistent approach to the education of patients, the evolution of the drug label has resulted in a tool that is frequently poorly suited to this task. The ability of national regulators to impose local changes, no matter how poorly supported by evidence, and diversity of approaches across geographies has resulted in labels for established products becoming tightly focused on individual markets.

Despite these shortcomings, the label will remain the core approved document for the product so companies will need to manage the changes to it more carefully in the future; resisting idiosyncratic local changes as much as possible, to enable more consistent communications to be created.

The label is not the only available tool, as long as they are consistent with it, other presentations of drug information are available which can be much more helpful in meeting the challenge of providing better patient education.



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Let's take a look at an example:

The first organisation to make successful use of the new EU switch process identified that education on safe use was the only way to ensure the right patients were using the product in the appropriate way; as a result a comprehensive programme was developed to support these objectives.

Not only was the wording of the label constructed with extreme care to ensure key messages were understood but the Patient Information Leaflet (PIL) and the pack reinforced messages on appropriate use. The organisation didn't stop there, but continued to look at the route by which the product would reach the patient – the pharmacy. Educational materials were developed for all those who could come into contact with the product resulting in packages supporting Continuing Medical Education, Pharmacist and assistant training modules and an associated consumer support programme, including websites and interactive forums, tailored to the legislation and pharmacy practices of each market.

The effectiveness of these interventions is measured through surveys which, together with traditional safety monitoring, are providing the company and regulators with the evidence on which to base decisions about changes to the programme and the products continuing success in the marketplace.

Nostrapharmus predicts; 'by 2020, the label will no longer be considered adequate on its own. The burden of usage must be shared, with a large proportion of that responsibility resting with the originator of the drug. Clearly any company looking to develop a comprehensive approach to patient education needs to be careful to ensure no inappropriate promotion takes place, and that actions are governed to adhere to local regulations. Once a patient is committed to using a product however, the level of support and interaction can go way beyond the traditional PIL in the pack to deliver a richer, more supportive and, ultimately, a safer experience for the customer.'

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