

## **1 Purpose**

The purpose of this Guideline is to describe the way in which artworks and printed package components should be created and controlled.

## **2 Scope**

This Guideline is applicable to all artworks and printed package components for inclusion in finished products.

## **3 Definitions**

### **3.1 Marketing Company**

The Marketing Company is the organization responsible for marketing products in a country. For the purposes of this Guideline the definition of a Marketing Company includes any manufacturing and/or packaging sites that may be part of the Marketing Company organization.

### **3.2 Packaging Site**

A site where the particular medicinal product is packaged and/or labeled to produce 'finished product'. A packaging site packing a product for a particular Marketing Company may be one of the following:

- a part of that Marketing Company organization
- a part of another contracted Marketing Company organization
- a company contracted to one of the above.

In the case of a larger Marketing Company that may have more than one packaging site in its organization, some of the responsibilities and activities identified in this Guideline may be discharged through a single group that acts for some or all these packaging sites.

### **3.3 Approved Text**

Any text approved by the regulatory department of a Marketing Company that will appear on printed package components, e.g. labels, leaflets, pre-printed ampoules, tubes, foils.

### **3.4 Graphic Design**

A decoration that will appear on a printed package component.

### **3.5 Physical Pack Design**

A diagram of a package component showing allowable print areas and non-print areas (that is, areas reserved for bar coding, variable data, glue flaps, etc.)

provide a physical pack design to the Marketing Company to use as a basis for an artwork.

- 4.3** It is the responsibility of the Marketing Company to ensure that artworks prepared on its behalf comply with the company's Graphics Policy, to obtain the external regulatory approvals necessary for the use of these artworks, or text contained therein, and to provide these fully approved artworks to the site where packaging activities will be carried out.
- 4.4** In the case of 'multi-market' packs, it is the responsibility of either the appropriate group in Regulatory Affairs or the Marketing Company elected to manage a particular 'multi-market' pack, to ensure that each pack complies with:
- Company's Graphics Policy
  - the requirements of company's Packaging Manual
  - the labeling text and artworks approved in each market that will receive the multi-market pack.
- 4.5** It is the responsibility of the packaging site to send the approved artwork to the printer and to assure the quality and correctness (based on the artwork provided) of printed components delivered from the printer.
- 4.6** It is the responsibility of all those identified in Sections 4.1 to 4.5 to collectively manage the replacement of superseded versions of artworks, printed components and associated packed stock with new approved versions, in a secure, timely and regulatory compliant manner.

The appointment of someone in each Marketing Company to co-ordinate all change management activities on artworks/printed components should be considered.

## **5 Guideline**

The responsibilities outlined above may be discharged through a variety of processes, with varying responsibilities within each Marketing Company and packaging site.

These processes and responsibilities should be described in local written procedures as outlined in the following sub-sections.

### **5.1 Preparation of Physical Pack Designs**

The packaging site should have written procedures in place to describe how physical pack designs are prepared, approved and provided to a Marketing Company.

### **5.2 Creation and Approval of Labeling Text, Graphics and Artworks**

The Marketing Company should have written procedures in place to describe the