CHAPTER FIVE

The graphic presentation of patient package inserts

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5.1 PATIENT PACKAGE INSERTS

Patient package inserts provide patients with information about a specific medicine. These inserts are developed and produced by the pharmaceutical industry, and are included in medicine packages. European regulations stipulate that every medicine must be accompanied by such an insert from January 1994 onwards (Directive 92/27/EEC, 1992). Approximately 40 000 different inserts have had to be produced.

There are two main reasons for supplying inserts to patients (Donnelly, 1991). The first is to increase the effective use of medicines. The supply of printed information could increase the patients' knowledge about their medicines (about the treatment, the instructions, and side-effects), and it could change attitudes of patients (improve satisfaction with a medicine, and influence a risk–benefit assessment). The provision of information could also increase appropriate medicine-taking behaviour (compliance), and increase the number of reactions from patients (reporting of side-effects, and questions asked). The second reason for supplying inserts is that the patient has a right to be informed.

Patients have three main purposes for reading inserts (Vander Stichele *et al.*, 1991). In the first place, patients seem to be interested in information about safety related matters, such as side-effects, and risks involved. Patients need this information to make decisions on whether to use a medicine or not. Secondly, patients consult an insert to find out how to administer a medicine. And thirdly, patients read inserts to find out about the indications of a medicine. This last information can reassure patients by confirming that the appropriate medicine has been prescribed. It also tells patients which effects could be anticipated and whether these effects are

positive or should be cause for concern. Patient package inserts have been extensively investigated by medical, pharmaceutical and linguistic researchers (see for example Bogaert *et al.*, 1989; Mann, 1991). Several investigations have shown that at least 75 per cent of patients say they read inserts (Gibbs *et al.*, 1989; Rupf, 1991).

The EU directive states that inserts should include the following seven information sections:

- Identification of a medicine (names, active ingredients, and the name of the manufacturer).
- Therapeutic indications.
- Information necessary before taking a medicine (contraindications, precautions, interactions and special warnings).
- Instructions for use (dosage, method and route of administration, and the duration of the treatment).
- Description of undesirable effects.
- Information about expiry date and storage instructions.
- Date of the most recent revision of the insert.

The choice of this list of sections is mainly based on common sense and some research results (see for example Joossens, 1989, 1993). The list still contains some historical remnants, which can be traced back to 1968, when the first patient-oriented warnings had to appear on medicine packages.

Although this list of information sections seems to provide a solid starting point for the development of inserts, there are many unresolved issues. For example, the discussion of what an undesirable effect actually entails and the way in which this should be worded is still ongoing. The situation regarding liability and copyright issues is also still unclear. However, despite these difficulties, it seems clear that the development of inserts is worth the effort simply because patients are happier with inserts than without them (Vander Stichele and Bogaert, 1989).

It should be clear that providing patient package inserts is only a small part of the process of supplying patients with information about their medicines. Most information is supplied orally by general practitioners or medical specialists during the consultation, or by pharmacists who dispense the medicines. Inserts are usually the only printed information available to patients, and they can only be read after a medicine has been acquired. It is therefore important to make these inserts as effective as possible.

One of the factors which influence the effectiveness of the use of inserts is the visual or graphic presentation. The graphic presentation of current patient package inserts seems to suggest, however, that they are considered to be of little importance. Not much has improved since Walter Modell wrote in 1967 that most inserts are 'printed in Lilliputian type on Bible paper, are hard to handle and very difficult to read' (Modell, 1967, p. 776).

5.2 A FRAMEWORK FOR THE DESCRIPTION OF GRAPHIC PRESENTATION

In order to discuss graphic presentation, it seems essential to distinguish between insert development and insert use. During development, complex medical information is transformed and presented in a single insert. The relation between the intended information content and the graphic presentation can be called 'concordance'. This process is reversed when inserts are used. A user looks at an insert and can extract information from it. The relation between the graphic presentation and insert use can be called 'suitability'.

In order to describe the concordance and the suitability of graphic presentation in inserts, it is essential to apply some sort of descriptive framework (for a brief discussion of several descriptive frameworks see Van der Waarde, 1993). Structured documents, such as inserts, are often described as a collection of objects. A description could initially try to describe the smallest (atomic) objects which might have an influence on insert use. This description of the smallest objects can be expanded to include a description of relations between these objects. A third level of description could encompass characteristics related to a complete document. The description which follows focuses on each of these three levels. The complete framework is illustrated in Figure 5.1.

5.2.1 Level 1 – graphic components

The first type of graphic component is the *verbal* component. A possible definition of verbal components is that they are all meaningful marks which can be pronounced. Common topics are the use of serif or sanserif typefaces, the justification mode, the dimensions of type (x-height, line space and capital height), the line length, the type weight, and the use of upper and lower case characters (see for example Luna, 1992). This is the most common type of graphic component in patient package inserts.

The second type of component is the *pictorial* component. A pictorial component is a graphic mark, or group of marks which relates, however distantly, to the appearance or structure of a real or imagined object (Twyman, 1985). Several taxonomies for this type of component have been developed (for example Goldsmith, 1984). The majority of illustrations in inserts show how a medicine should be administered. However, pictorial components rarely occur in inserts.

The third type of graphic component is the *schematic* component. Schematic components are separable graphic marks which cannot be categorized as either verbal or pictorial. Examples of schematic components are rules, bullets, arrows and background colours. Schematic components can only be used in combination with other types of graphic components. The most common schematic component in inserts is a single line border around verbal components.

The fourth type is the *composite* component. A composite component is a configuration of graphic marks which cannot be further separated, but can consist of any combination of verbal, pictorial and schematic components. Examples of

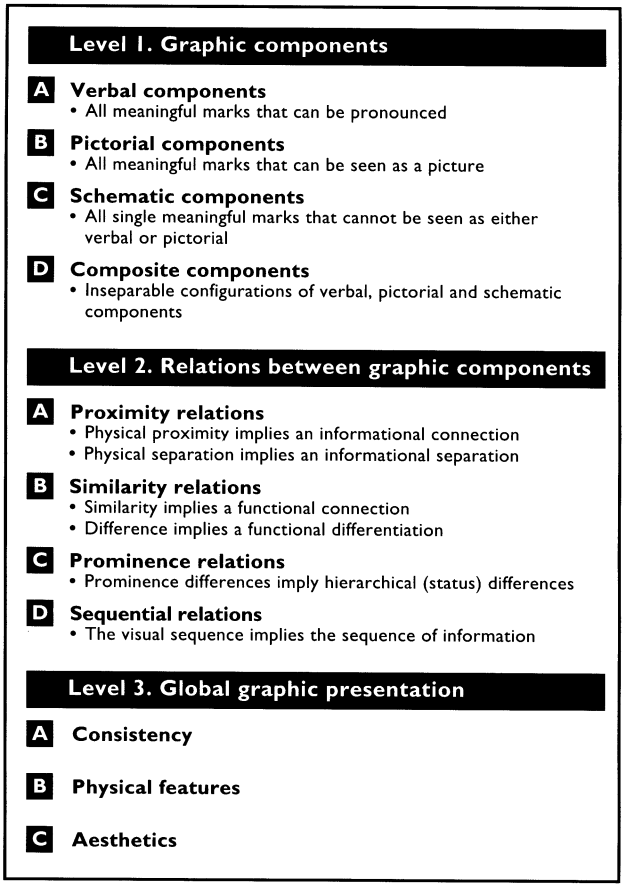

Figure 5.1 Framework for the description of graphic presentation.

composite components are diagrams, charts, tables and annotated illustrations (see for example Weidenmann, 1994). Composite components are very rarely used in inserts.

The distinction between these four types of graphic components is not an absolute division. For example, some pictograms can be classified as pictorial, or as schematic, or as composite components. However, these four types of components are sufficient for an initial description of the smallest graphic objects in inserts.

5.2.2 Level 2 – relations between components

The first relation, *proximity*, refers to the distance between graphic components. Graphic components which are positioned close together suggest that there is a strong relation between information elements; components which are positioned further apart are less related. This type of relation is frequently described as the grouping of information, or the use of space (see for example Hartley, 1994). Figure 5.1

illustrates this relation. In this figure the first level consists of four groups. Each group consists of a reversed capital letter, a bold text, and a roman text. Only the distance between these elements determines this grouping arrangement.

The second relation between graphic components is the *similarity* of graphic components. A visual similarity is an indication of a functional kinship: components which look similar have a similar hierarchical status. Graphic components which look different present information elements with a different status. In Figure 5.1 the reversed headings are purposefully made to look similar, thereby indicating that the information is on the same hierarchical level (for a discussion of the similarity principle see Medin *et al.*, 1993).

The third relation can be described as the *prominence* relation. The prominence differences between graphic components is an indication of the amount of difference in hierarchical status between information elements. The larger the contrast between graphic components, the larger the difference in status of information (Dobson, 1979). In Figure 5.1 the difference in prominence between the bold and the roman version of the typeface indicates the amount of difference in status of these elements.

The fourth relation is the *sequential* relation. The sequence of the graphic components indicates the succession of the information elements. In printed information, this sequence is to a large extent determined by the reading direction (Winn, 1993). In Figure 5.1 the information elements follow each other vertically downwards.

These four relations are interrelated: changing one will affect the others. It is thereby necessary to take into account that the sequence of the information sections in inserts is determined by the EU directive.

5.2.3 Level 3 – the global graphic presentation

At least three characteristics of the global graphic presentation of an insert have to be considered. These characteristics are important because they provide the reader with a first impression of the information content of an insert.

A first characteristic is the *consistency* of the application of graphic variables in a document. A consistent use of graphic components and relations between components throughout an insert can make the information structure easier to grasp.

A second characteristic is the *physical features* of a document. For example, the dimensions of the document, the paper quality, printing inks, shine-through and reflection can be described.

The last characteristic related to the overall graphic presentation is the *aesthetic aspects* of inserts. These aspects are probably the most difficult ones to describe, but they are mentioned most often in relation to graphic presentation.

5.3 DESCRIBING THE GRAPHIC PRESENTATION OF INSERTS

The purpose of the development of a graphic presentation is to construct an insert which is maximally effective. The most effective graphic presentation is achieved

when as many readers as possible can be accommodated by a single insert. The suggested framework may be helpful in two ways.

Firstly, the framework provides an approach for organizing discussions (e.g. between clients and designers) which try to establish whether a specific graphic presentation is the most appropriate in representing information about medicines in inserts (concordance). A systematic approach may make the integration of general design guidelines and experimental evidence possible. Looking at the most recent inserts, there seem to be three shifts:

- The amount of verbal components is reduced in favour of the other three types of components.
- The relations between graphic components are exploited to visualize relations between information elements.
- The general factors are considered in order to provoke a more favourable impression.

Secondly, the framework could be used to investigate the influence of graphic presentation on insert use. Each component, relation between components, and overall characteristic can be modified to improve the effectiveness of graphic presentation (suitability). Empirical studies and usability tests need to be undertaken to establish the influence of graphic presentation on the effectiveness of inserts.

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