Ergonomics in drug labeling: an analysis from principles of visual comfort

Arina Blum¹, Eugenio Andrés Díaz Merino², Giselle Schmidt Alves Díaz Merino³

Universidade Federal de Santa Catarina, Campus Universitário Reitor João David Ferreira Lima, Centro de Comunicação e Expressão, Bloco A, Sala 113, Caixa Postal 476, Trindade, Florianópolis, SC, Brasil, 88040-970

1 arinablum@gmail.com, 2 eugenio.merino@ufsc.br, 3 gisellemerino@gmail.com

Keywords: ergonomics, packaging, drug

1 Context

The construction of visual messages is directly related to the knowledge, attitudes and people's behavior, and, by design, there is the development of strategies that use visual elements to implement and identify something (FRASCARA, 2000). The development of packaging is applied in this context, and the packaging is made up of specific functions related to technological and marketing status, logistic, economic and functional aspects, purpose, protection, appearance and concept (GURGEL, 2007). The package has the role to protect the product and to help consumers to use it, as well as to inform.

The package, included among the traditional informational graphics systems, can have problems regarding ergonomic aspects, resulting in the impairment of effective perception of information (PASCHOARELLI; BONFIM, 2013). Hellebek (2013), concerning drug packaging, states that patient safety is also related to it, as medication errors may be the result of problems of interaction with the user. Amending the label design can improve the patient's safety who is already in the medication process and it is relevant to analyze the relationship of misinterpretation of labels with the design of these labels.

In the case of drugs in Brazil, the rules of the Brazilian Health Surveillance Agency (Anvisa) establish guidelines, the RDC 71/2009, that aim at "improving the form and content of labels of all registered drugs sold in Brazil, with the objective of ensuring access to secure and suitable information to promote the rational use of drugs" (BRA-SIL, 2009). This is a technical regulation that rules the labeling of drugs registered in the Ministry of Health. In the RDC 71/2009, Anvisa communicates packaging models that help manufacturers regarding the standardized visual guidelines, while explain (visually) the elements laid out in the regulations.

2 Method

The objective of the research reported in this article was to analyze the visual ergonomic issues related to the label of drugs using principles of visual ergonomics - specifically guidelines that point to aspects of legibility in packaging – from specialized literature. Starting from the question whether definitions that concern visual ergonomics are contemplated in the rules that specify the labeling of drugs, the analysis was structured through an exploratory qualitative research of applied nature.

As methodological procedures, from a literature review, principles of visual ergonomics in the context of legibility, readability and visibility, were collected and used as indicative for the study of a drug package. Also, analyzing documents which rule the drug labeling, the research focused on a specific model of secondary packaging presented by the Ministry of Health, understanding that this is a model which, among others, visually represents the transposition of the rules presented in the Brazilian Health Surveillance Agency (Anvisa) guidelines.

3 Results

The research consisted of a comparative analysis from recommendations available in literature – related to visual ergonomics in graphic material - in relation to a proposed secondary packaging model in the "Manual de Embalagens de Medicamentos" (BRASIL, 2012). The study focused on the analysis of the frontal part of the packaging, considering this to be an initial research of a further investigation, and also with the assumption that the frontal part of the package is the one that first identifies it to the consumer.

Indicative of the following materials were used: Farias (2013); Fontoura; Fukushima (2012); Gomes Filho (2012); Kamisaki; Nascimento; Santos (2011); European Commission (2009); Lima (2007); Dondis (2007); Iida (2005); Plain English Campaing (2001 e 2007); Committee on Safety of Medicines (2005). From these references, thirty indications were established: (1) simple letters - sans serif or little serif; (2) Uppercase letter only at the beginning of the sentence; (3) letter height over 4 mm to 60 cm distance; (4) Leading at least 1/30 of the length; (5) Text alignment left; (6) No hyphen; (7) No small caps; (8) Types with contrast in the shape of letters; (9) Types with highlighted ascendants and descendants (10) No condensed; (11) No extended; (12) The length of the line; (13) No italic; (14) Variation in the design of types; (15) Use of symbols and / or clear pictograms; (16) Color is not the only way to understand information; (17) Reading from left to right; (18) Hierarchy of information; (19) suitable margins; (20) Space forming information blocks; (21) No watermarks; (22) Background-image contrast; (23) (Gestalt) Unit; (24) (Gestalt) Segregation; (25) (Gestalt) Unification; (26) (Gestalt) Shutdown; (27) (Gestalt) Continuity; (28) (Gestalt) Proximity; (29) (Gestalt) Similarity; (30) (gestalt) Symmetry.

Focusing on checking whether the analyzed packaging was in accordance with each of the thirty indications or new studies should be undertaken to improve some aspects, there were highlights with favorable opinion - that is, according to the propositions indicated in literature - the requirements listed in items 1; 5; 6; 7; 8; 11; 12; 14; 16; 17; 19; 20; 21; 24; 26; 28. And among the opinions that suggest to carry out further studies in relation to the proposed characteristics they are: 2; 3; 4; 9; 10; 13; 15; 18; 22; 23; 25; 27; 29; 30.

4 Conclusions

The analysis indicated that in the drug packaging studied and by what is stated in the regulations, there are concerning points to what is proposed in literature and others that point out the need for a specific and continuing review in the study of other labels. Furthermore, limitations related to the aspects which concern the definition of "legibility" and additional studies on its relation to the readability and visibility - even in terms of its approach to the Brazilian legislation in the health area - showed, from this study, that the research on drug labeling requires a partitioned approach, so as to deepen a theoretical corpus yet under construction. We conclude that this study is an initial part of many aspects linked to the informational design applied in the field of health and packaging. From the present research, other steps will lead to the generation of studies which support the practice of design as a communication means on drug labeling, and consequently, in order to corroborate with consumer's safety.

5 References

- 1. BRASIL. Rdc nº 21, de 28 de março de 2012. **Rdc 21/2009 Anvisa**: Institui o Manual de Identidade Visual de Medicamentos do Ministério da Saúde e dá outras providências. Brasília, DF, 2012.
- 2. BRASIL. Rdc nº 71, de 22 de dezembro de 2009. **Rdc 71/2009 Anvisa** : estabelece regras para a rotulagem de medicamentos. Brasília, DF, 2009.
- 3. COMMITTEE ON SAFETY OF MEDICINES (Reino Unido). Medicines And Healthcare Products Regulatory Agency. **Always Read The Leaflet:** Getting the best information with every medicine. Norwich: The Stationery Office, 2005.
- 4. DONDIS, Donis A. Sintaxe da linguagem visual. 2. ed. São Paulo: Martins Fontes, 2007.
- 5. EUROPEAN COMMISSION. Guideline on the readability of the labelling and package leaflet of medicinal products for human us: Revision 1, 12 January 2009. Bruxelas: European Commission Enterprise And Industry Directorate-general, 2009.

- 6. FARIAS, Priscila L. **Tipografia digital:** impacto das novas tecnologias. Teresópolis: 2ab, 2013.
- FONTOURA, Antônio M.; FUKUSHIMA, Naotake. Vade-Mécum de tipografia. Curitiba: Insight, 2012.
- 8. FRASCARA, Jorge. **Diseño gráfico para la gente.** Buenos Aires: Ediciones Infinito, 2000.
- 9. GOMES FILHO, João. **Gestalt do Objeto:** Sistema de Leitura Visual da Forma. 9. ed. São Paulo: Escrituras, 2012.
- 10. GURGEL, Floriano do Amaral. Administração da embalagem. São Paulo: Thomson Learning, 2007.
- HELLEBEK, Annemarie et al. Patient safety in drug label design: analysis of reported adverse events before and after introducing a new label design. European Journal Of Hospital Pharmacy, London, v. 20, n. 4, p.212-217, ago. 2013.
- 12. IIDA, Itiro. Ergonomia: projeto e produção. 2. ed. São Paulo: Blucher, 2005.
- KAMISAKI, Margareth Sayuri; NASCIMENTO, Roberto Alcarria do; SANTOS, João Eduardo Guarnetti dos. Bulas e Cartelas de Medicamentos: Possíveis soluções de leiturabilidade através do Design Gráfico. Arcos Design, Rio de Janeiro, v. 6, n. 1, p.42-59, dez. 2011.
- LIMA, Vera Lopes de Abreu. Legibilidade e leiturabilidade das bulas de medicamentos presentes no tratamento de pacientes cardíacos. 2007. 1 v. Dissertação (Mestrado) -Curso de Design, Pontifícia Universidade Católica do Rio de Janeiro, Rio de Janeiro, 2007.
- PASCHOARELLI, Luis C.; BONFIM, Gabriel H. C.. Ergonomics and interfaces of traditional information systems: Packaging. Infodesign: Revista Brasileira de Design da Informação, São Paulo, v. 10, n. 3, p.313-322, dez. 2013.
- 16. PLAIN ENGLISH CAMPAIGN. Guide to design and layout. New Mills: Plain English Campaign, 2007.
- 17. PLAIN ENGLISH CAMPAIGN. How to write medical information in plain English. New Mills: Plain English Campaign, 2001.

6 Acknowledgments

To the Coordination for the Improvement of Higher Education Personnel (CAPES), Graduate Program in Design at the Federal University of Santa Catarina

Ergodesign & HCI

número 2, volume 3, ano 3 (2015) ISSN 2317-8876, Rio de Janeiro - Brasil PUC-Rio Pontifícia Universidade Católica do Rio de Janeiro Departamento de Artes & Design | PPGDesign LEUI | Laboratório de Ergodesign e Usabilidade de Interfaces

(UFSC), the Management Center for Design and the Design and Usability Laboratory at UFSC (NGD-LDU/UFSC).