## Automatic Quantification of Abbreviations and Symbols in Medicinal Package Leaflets and Assessment of their Comprehension

CARLA PIRES

iMed, Instituto de Investigação do Medicamento, Faculdade de Farmácia, Universidade de Lisboa

MARINA VIGÁRIO

Faculdade de Letras, Universidade de Lisboa

FERNANDO MARTINS

Faculdade de Letras, Universidade de Lisboa

AFONSO CAVACO

iMed, Instituto de Investigação do Medicamento, Faculdade de Farmácia, Universidade de Lisboa

## **ABSTRACT**

Introduction: There are reports of severe medication errors, as a consequence of misunderstandings with their use. Given pharmaceutical regulations, medicine package leaflets (PLs) should not contain abbreviations and symbols (A&S).¹ Importantly, A&S of units of measures should be presented using the following formats: 1) x mg/ml = concentration; 2) z mg = total active substance; 3) y ml = total volume; and 4) z mg/y ml = total active substance per total volume.²³ Research question/problem: Are A&S presented in PLs of Portuguese medicines? Are non-recommended formats of units of measure available in these PLs? Do educated people comprehend some of these A&S? Objectives: Using a representative sample of 531 Portuguese PLs, the aims of this study were: to quantify A&S, to identify non-recommended units of measure, and to determine educated peoples' interpretation of A&S. Methods: A&S, including A&S of non-recommended units of measure were quantified with a computational tool — PreText: Text Preprocessing.⁴ A questionnaire was applied to determine participants' comprehension. It was only evaluated the comprehension of 373 A&S to avoid tiring the participants. Overall, 26 undergraduates from non-biomedical areas were enrolled in this study.

**Results:** A total of 828 different A&S were identified (6407 occurrences). Overall, 14 non-recommended formats of units of measure were identified (38, 0.6% of 6407 occurrences). Only, 9.9% of all the replies of the comprehension questionnaire were classified as correct. **Conclusion:** Portuguese PLs may need to be revised in relation to the use of A&S and the format of units of measure. The software proved to be an efficient tool to check A&S in PLs.

Keywords: package leaflets; readability; medicinal products; abbreviations; patient safety

Abstract of the research project presented at International Meeting of Doctoral Students in Nursing of Universidade de Lisboa, May 2016.

Automatic
Quantification of
Abbreviations and
Symbols in Medicinal
Package Leaflets and
Assessment of their
Comprehension

## REFERENCES

- FDA Food and Drug Administration. (2013). Guidance for Industry, Labelling for human Prescription Drug and Biological Products Implementing the PLR content and Format Requirements. Retrieved October 17, 2015, from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075082.pdf
- EMA European Medicine Agency. (2009a). Guideline on the readability of the labelling and package leaflet of medicinal products for human use. Retrieved October 17, 2015, from http://ec.europa.eu/health/files/eudralex/vol-2/c/2009\_01\_12\_readability\_guideline\_final\_en.pdf
- EMA European Medicine Agency. (2009b). Quality review of documents group (QRD). Qrd recommendations on the expression of strength in the name of Centrally authorised human medicinal products. Retrieved October 17, 2015, from http://www.ema.europa.eu/docs/en\_GB/document\_library/Regulatory\_and\_procedural\_guideline/2010/01/WC500056428.pdf
- Martins, F., Vigário, M., & Frota, S. (2015). PreText Text Preprocessing, version 1. Lisbon: Phonetic Laboratory, CLUL/FLUL. An updated version may be accessed at http://labfon.letras.ulisboa.pt/FreP/tools.html. [Accessed 4 February 2016].

Contact: cmbpires@ff.ul.pt