Evaluation of Differences in Global Over-The-Counter Drug Product Labeling

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Background:

Over-the-counter products represent a significant value to the consumer. They provide access to medicinal products that can improve a patient's quality of life. Consumers currently have the ability to self-treat numerous mild-moderate conditions from categories such as pain, cough/cold, gastrointestinal ailments, allergies, topical infections, and more. In the United States, consumers must be provided with certain information and directions for use. This information is presented within the labeling of the product, known as "Drug Facts" in the US. It is suspected, however, that the type, format, and extent of the information provided therein may not be fulfilling its goal of fully educating consumers. To begin to examine this, this study compares the labeling practices in the United States to those of other countries. This study does not aim to evaluate label comprehension.

Purpose:

Evaluate the differences in over-the-counter product labeling practices between the United States and other countries.

Methods:

Primary variable: Total Score, comprised of a content score (40%) + accuracy score (20%) + user-friendliness score (40%), all calculated on 100-point scales.

Scoring:

Mean ± Standard Deviation calculated for all groups and scores

Content score:

Inclusion of key topics (IKT): Active ingredient, product uses, excipients, directions, warnings, adverse events, storage, contact information

Balance score: Uses, directions, warnings, and adverse events

Accuracy score:

10 points subtracted for each error

User-friendliness score:

Usability score (legibility): Font size and color scored on 5 point categorical scales, (Size + Color) x 10

Logic score: Points given if subject falls within 3 position ordering (Ex. Active ingredient: 1st, 2nd, or 3rd)

Inclusion Criteria

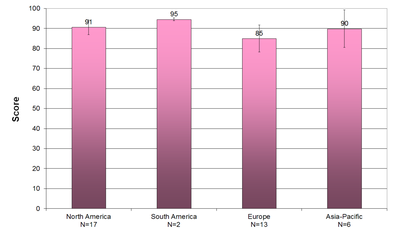
- Must contain a currently marketed active ingredient which is recognized either within a monograph or through an NDA in the United States.
- Available in English and/or a translation was done by a professional.
- Available in product flat format, either digitally or physically.
- Must be marketed in ≥2 countries.
- Must represent the information visible to the consumer at the time of product selection. Product information inserts will not be included in this study.

Exclusion Criteria

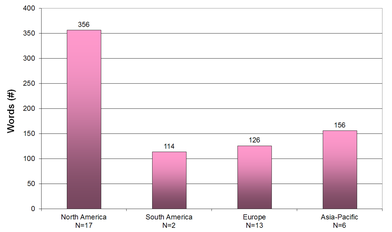
- Multiple labels of the same active ingredient from the same manufacturer but in different doses or count sizes will be excluded except wherein a material difference is found between the labeling of the different dosages.
- Nutritional supplements will not be included as the labeling requirements for these products differ.
- Labels for ingredients which are not available in the United States.
- Combination products will not be included.

Results:

A



B



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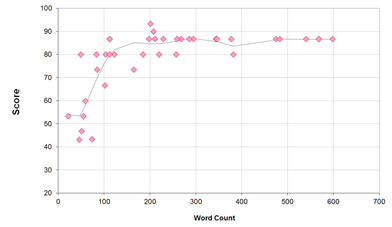

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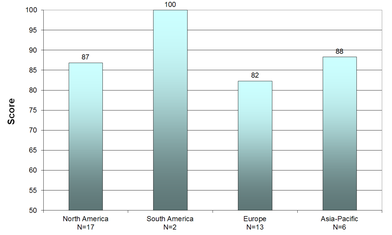

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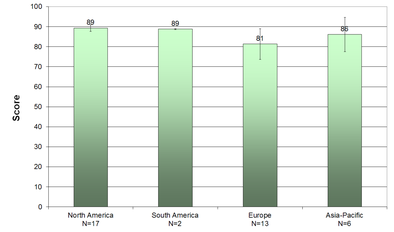

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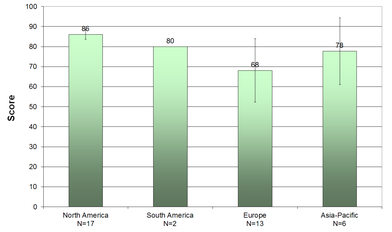

Conclusions:

Total scores (Figure A) were not significantly different between regions. The sub-scores that make up the total score revealed larger differences.

North American (NA) labels present the largest volume of information to consumers at the time of purchase (Figure B). NA labels also had a higher proportion of packaging devoted to labeling. In general, NA labels produced less variable results than the other regions, as demonstrated by the standard deviations of the data sets (Figures E, F).

European labels tended to produce lower and more highly variable scores than labels from the NA region. This is particularly evident in Figure F. Furthermore, labeling information tended to be presented less logically in this region, with no consistent format even within countries. This is a result of the large number of health authorities in the region as well as the broad usage of package inserts.

Too few labels were acquired from the South American and Asian regions to allow for more definitive conclusions.

Limitations of this analysis include:

- Labels from non-Bayer companies are much less well represented.
- A limited number of labels from the SA and AP regions. As a result, only qualitative observations could be made for individual countries.
- Evaluations were conducted by the principal investigator alone and the possibility of bias cannot be excluded.
- This analysis was purely focused on identifying overall patterns in labeling and therefore it is inappropriate to speculate as to the effectiveness with which the information on the label is communicated to consumers.

Overall, labels presented minimal adverse event information to consumers. Instead, labels focused on warnings, which are predominantly precautions and contraindications. This is an area for improvement, as consumers should be aware of common adverse reactions associated with the use of medicinal products.

This analysis suggests that harmonization of labeling format could be beneficial for the EU and possibly SA regions. While this change appears logical with respect to the format of labels, the content of said labels would be much more difficult to standardize.

References:

Winterstein AG, Linden S, Lee AE, et al. Evaluation of Consumer Medication Information Dispensed in Retail Pharmacies. Arch Intern Med. 2010;170(15):1317-24.

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Disclosures:

SG is a post-doctoral fellow at Rutgers University whose sponsor company is Bayer HealthCare LLC.

MF is an employee of Bayer HealthCare LLC.

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