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-to-moderate conditions, 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.

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 scores (40%), all calculated on 100-point scales.

Scoring:
Mean ± Standard Deviation calculated for all groups and scores

Content score:
Inclusion of key topics (K): Active ingredient, product uses, excipients, directions, warnings, adverse events, storage, contact information.
Balance score: Uses, directions, warnings, and adverse events
Accuracy score:
10 points withheld per error

User-friendliness score:
Usability score (legibility, Font size and color scores) on 5-point categorical scales. (Sloan & Cohn’s Y’s) 10 Logic score: Points given if subject falls within a 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.
Available in English and/or a translation was done by a professional.

Exclusion criteria:
Combination products will not be included.
Labels for ingredients which are not available in the United States.
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.

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 labels from some European countries in the top three regions.

This analysis suggests that harmonization of labeling format could be beneficial for the EU and possibly SA regions. 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.

While this change appears logical with respect to the format of labels, the content of said labels would be much more well-stocked.

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. It is an area for improvement, as consumers should be aware of common adverse reactions associated with the use of medicinal products.

References:

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