Evaluation of medication package inserts

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Introduction

Written patient drug information, such as package inserts (PIs), is intended to instruct patients on how and when to use a medicine and to promote an understanding of the purpose, benefits and risks of the medication prescribed (1).
This understanding is supposed to lead to successful therapy and enable safe medication use.

Methods

60 medications (prescription = 37 and OTC = 23) were chosen from the top 150 sold medications in Saudi during the year 2011.
The medicines cover 15 therapeutic indications and different pharmaceutical forms (tablets, capsules, syrups, suspensions).
The PI for each medicine was obtained in hardcopy.

Six PI characteristics were examined: dimensions, layout, type of paper, color of paper and text, transparency, use of headings, and use of pictograms or graphics.
PI content was evaluated using criteria derived from the literature.

The data were extracted by the author twice at different times to minimize the chances of missing any information.
The number of PIs that met the quality criteria was calculated. Full details of the methodology is available in the published study (2).

Results

Five (8%) PIs used images, pictograms, or other graphics. Abbreviations and acronyms other than “mg,” “mL,” or “kg” were used in 21 (35%) PIs. Scientific symbols (such as “>” or “<”) were used in 19 (32%) PIs.
The explanation for medical terminology was available in eight (13%) PIs.

All PIs contained information on name, active ingredients, therapeutic indications, and pharmaceutical forms.
Although all PIs provided precautions and adverse effects information, many lacked important information (Table below)

Precautions	**n (%)**
Statement of contraindications	58 (97)
Statement of drug interactions	47 (78)
Provides advice on when to consult a physician/pharmacist	21 (35)
Adverse effects	
Provides qualitative statements on the frequency of side effects (rare or common)	38 (63)
Verbal frequency terms are explained in the form of natural frequencies, eg, very common “more than 1 in 10 patients	10 (17)
Describes severity of every possible adverse reaction	8 (13)
Setting out the side effects by frequency of occurrence, starting with the highest	17 (28)
Describes suitable measures in case of adverse reactions	16 (27)
Possible side effects if medication is stopped or the dose is changed without doctor’s advice	5 (8)

Conclusions

This study indicates that information relevant to the safe and appropriate use of medications was not uniformly provided In the PIs analyzed.

To avoid medication errors due to deficits in the current PIs, we recommend improvement in the existing PI is based on best practice for information content and design.

References

1. Health Technol Assess. 2007;11(5):iii, 1–160.
2. Drug, Healthcare and Patient Safety 2012:4 33–38