Background and objective:

Medication package insert (PI) that is written for patients is a well-chosen drug information source that is formed and arranged to supply patients with information about how to use medications safely and effectively to reach the required therapeutics outcomes. This comparative study was conducted to evaluate Antihistamines PIs that are produced in Palestine with their imported equivalents.

Methods: Seventeen PIs of oral antihistamines were analyzed and evaluated. Thirty-one terms were obtained from literature and used; evaluation was performed on basis of presence/absence of these terms in the leaflets. Out of 31 terms 23 criteria were chosen as the two studied groups mentioned these and were meaningful to be counted and compared; then the median word count for each related section was determined separately for the two groups and used for comparison.

Results: Seventeen antihistamine (H1 blockers) PIs that are available on Palestinian pharmaceutical market were analyzed based on 31 criteria. Among those inserts 8 (47%) were local products and 9 (53%) were imported. The 9 locally produced agents are manufactured by 4 Palestinian pharmaceutical companies specified as A (3 products), B (2 products), C (3 products), D (one product). Upon analysis and as table 2 illustrated, we found that all antihistamine PIs (100%) mentioned brand name, active ingredient, therapeutic class, indication, drug dose, warning and precaution, contraindication, storage and name and address of manufactures /distributors. Most PIs for (H1 blockers had information regarding adverse drug reaction (94%), drug-drug interaction (88%), pregnancy considerations (94%) lactation considerations (71%), missing dose (77%), ability to drive and use machines (65%) pediatric considerations (59%), information regarding duration of use, excipients, possibility of tablet spitting, possibility of crushing and mixing with food and beverages presented in 29%, 53%, 12%, 12% of all PIs respectively. Information regarding date of last revision, references, geriatric considerations, drug-food interaction were not mentioned in any local products, whereas pharmacokinetic information, mechanism of action and maximum dose headings was not mentioned by any imported products. In general, the number of local leaflets that met the listed criteria was lower than the number of the imported one.

Conclusions: This study showed that local products provide less information than imported products, so we recommend appropriate measurements to be taken by Palestinian authorities and local manufacturers to improve both quantity and quality of local PIs.

Keywords: Package insert; oral Antihistamines; Palestine; Comparative; Local; Imported