

# GMP, GCP & QUALITY CONTROL

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# PHARMACEUTICAL REGULATORY AFFAIRS AND IPR

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## Assessment of the readability, understandability, informational contents' conformity and usefulness of medication package inserts to Sudanese patients

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**Statement of the Problem:** To use their medications properly and safely, patients need comprehensive and understandable medication information. Such information is usually provided in verbal, written and/visual forms. The medication package inserts are the most accessible and available written form of medication information. In Sudan at least 10 original brands and branded generic products, for the same generic name are registered. To secure their readability, understandability and usefulness, the package inserts of different produce for same generic name are supposed to show consistency in their typographic particulars, informational quantity, quality and contents and be written in lay native language with minimum technical terms. The purpose of this study was to assess the readability, understandability, informational contents' conformity and their ultimate usefulness to patients.

**Methodology:** Two equal sets of thirty one (n=31) package inserts, for same generic names of different products of European and developing countries were compared using seven core indicators namely: The texts' language, total words count, area (size) to the nearest cm<sup>2</sup>, font size, leading in points, total availability of section headings and the presence of nine defined medications section headings.

**Findings:** Showed significant differences between the words counts and area size of the two groups of package inserts (P value=0.0000 for both) and significant differences (P value<0.05) between five of the nine defined section headings, namely, inactive ingredients, use during pregnancy, over dose and management, use after expiration, Date and date of last version. Majority (67.74%) were written in English (foreign language) with much technical terms.

**Conclusion:** Studied package inserts' informational contents, texts typographic particulars, language and terminology, showed clear inter-product non-conformity which might compromise their readability, understandability and usefulness to patients.

**Recommendations:** To secure package inserts' usefulness to patients, their design, typographic particulars, informational contents, text's language and terminology shall be standardized.

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