

**ANALYSIS OF PACKAGE LEAFLETS AND THE CONTRIBUTION TO THE RATIONAL
USE OF MEDICATION**

**ANÁLISE DAS BULAS E A CONTRIBUIÇÃO PARA O USO RACIONAL DE
MEDICAMENTO**

**ANÁLISIS DE PROSPECTOS Y CONTRIBUCIÓN AL USO RACIONAL DE LOS
MEDICAMENTOS**

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ABSTRACT

Objective: To evaluate how package inserts have influenced correct use and treatment adherence. **Introduction:** Package inserts are based on medication information submitted to the National Health Surveillance Agency for subsequent approval. High rates of illness among the population and the prevalence of chronic diseases have also increased irrational medication use.

Method: A qualitative literature review of medication package inserts was conducted. The databases used were: Scielo, BVS, and PubMed. The descriptors used were: "Package insert," "Drug package insert," and "Rational use."

Results and discussion: The majority of drug users in Brazil are elderly, providing data that demonstrates that this population has more health problems and chronic diseases. It is estimated that 35% of the ingredients are used for self-medication.

Conclusion: It is concluded that package inserts are very important in the lives of medication users and therefore must be clear and easy to interpret to assist in correct therapy, as well as inform about the harmful effects, contributing to the rational use of medications.

Keywords: Bull. Medication Insert. Rational Use of Medicines.

RESUMO

Objetivo: avaliar como a bula têm influenciado na utilização correta e como isso afeta na adesão ao tratamento. **Introdução:** As bulas baseiam-se nas informações sobre os medicamentos enviadas à Agência Nacional de Vigilância Sanitária para depois serem aprovadas. Altas taxas de adoecimento da população e a prevalência de doenças crônicas, aumentou-se também o uso de medicamento de forma irracional.

Método: Foi realizado uma revisão de literatura, com abordagens qualitativas, sobre as bulas de medicamentos. As bases de dados utilizadas foram: Scielo, BVS e PubMed. Utilizou-se os descritores: "Bula", "Bula de medicamento", "Uso racional".

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Resultados e discussão: A maioria dos consumidores de fármacos no Brasil são as pessoas idosas, trazendo dados que comprovam que essa população tem mais problemas de saúde e doenças crônicas. Valores estimados que 35% dos insumos sejam utilizados pela automedicação.

Conclusão: Conclui-se que as bulas são muito importantes na vida dos usuários de medicamentos e por isso deve ser clara e de fácil interpretação para auxiliar na terapêutica correta, bem como informar sobre os malefícios, contribuindo para o uso racional de medicamentos.

Palavras-chave: Bula. Bula de Medicamento. Uso Racional de Medicamento.

RESUMEN

Objetivo: Evaluar cómo los prospectos han influido en el uso correcto y la adherencia al tratamiento. Introducción: Los prospectos se basan en la información sobre medicamentos presentada a la Agencia Nacional de Vigilancia Sanitaria para su posterior aprobación. Las altas tasas de enfermedad en la población y la prevalencia de enfermedades crónicas también han incrementado el uso irracional de medicamentos.

Método: Se realizó una revisión bibliográfica cualitativa de prospectos de medicamentos. Las bases de datos utilizadas fueron: Scielo, BVS y PubMed. Los descriptores utilizados fueron: "Prospecto", "Prospecto del medicamento" y "Uso racional".

Resultados y discusión: La mayoría de los consumidores de drogas en Brasil son adultos mayores, lo que demuestra que esta población presenta más problemas de salud y enfermedades crónicas. Se estima que el 35% de los ingredientes se utiliza para la automedicación.

Conclusión: Se concluye que los prospectos son muy importantes en la vida de los consumidores de medicamentos y, por lo tanto, deben ser claros y fáciles de interpretar para facilitar una terapia correcta, así como para informar sobre los efectos nocivos, contribuyendo así al uso racional de los medicamentos.

Palabras clave: Bol. Inserto de Medicamentos. Uso Racional de Medicamentos.

1 INTRODUCTION

The package inserts, labels, and tags have the important role of informing and guiding users about the product, as well as instructing about side effects and harm they can cause. The package inserts are based on the information on the inputs sent to the National Health Surveillance Agency, after being checked and approved (Fujita *et al*, 2014).

The process of regulating the medicine package insert began in Brazil in **1946**, when the Ministry of Health (MS) issued Decree No. 20,397, which regulated the Pharmaceutical Industry. From then on, the package inserts began to have information about the drugs and this depended on each laboratory. Over the years and technological advances, the package inserts have been reevaluated and improved, with the intention of transmitting adequate and easy-to-understand information to users (Caldeira *et al*, 2008).

With high morbidity rates and the prevalence of chronic diseases, the use of drugs has also increased, often irrationally, a problem that affects the entire sphere of health care. With the difficulty of reading and interpreting the package inserts, adherence to the medication decreases, causing problems related to pharmacotherapy.

Thus, it is necessary that the drug package insert be prepared with all users in mind, containing the information in a clear and objective way, with less technical terms, knowing that the vast majority who use it are people with little education. (Fujita *et al*, 2014).

Therefore, the objective of this study was to evaluate how the package inserts of the drugs have influenced the correct use and how this affects treatment adherence.

2 METHOD

For the present study, a literature review was carried out, with qualitative approaches, on the package inserts used by the Brazilian population and how this reflects on the rational use of medicine. The inclusion criteria were articles in Portuguese, articles appropriate to the theme and published in the last 20 years. The databases used were: Scielo, VHL and PubMed. The following descriptors were used: "Leaflet", "Drug leaflet", "Rational use". This study does not require going through the ethics committee because it is a literature review.

3 RESULTS AND DISCUSSION

The largest consumers of drugs in Brazil are the elderly, bringing data that prove that this population has more health problems and chronic diseases, causing them to use more drugs continuously, and often irrational use (Silva *et al*, 2022).

According to Silva *et al*, 2012, the use of medicines by the elderly in the age group of 70 years or older than in the younger age group, and substances for cardiovascular use, according to him, is due to the lack of care in youth or because these are diseases that affect more people at this age. Another important factor is the significant use of vitamins and supplements, and little established evidence on risk and benefit.

Another important fact is that elderly people have physiological changes, such as liver and kidney functions, which are part of the mechanism of action of medications, thus hindering the pharmacokinetics and pharmacodynamics of medications and, at other times, possible disorders to the health of the elderly (Silva *et al*, 2022).

The literature shows us that self-medication can lead individuals to many problems related to medications and this is due to polypharmacy, the indiscriminate use of drugs, purchase without a prescription, lack of evaluation by qualified professionals and the supplies sold without a prescription, within everyone's reach, ends up negatively influencing (Silva *et al*, 2022).

The incessant search for medicines makes individuals find indications through internet searches, with easy access to purchase and use, without worrying about the harm that this can cause. Estimated values of 35%, whether of the inputs used by self-medication (Bohomol and Andrade, 2020).

To avoid self-medication and irrational use of medications, it is recommended that people read the package inserts carefully and attentively, as it is the means of information and health promotion, also promoting the rational use of medications (Brasil, 2025).

The package inserts are also important to guide the patient regarding the use of a substance to which he is allergic, or that may interfere with the use of other medications. Package inserts must contain information on: prescription, doses, preparation, administration and warnings. There are also two more types of package inserts: The Special Format, which is intended for people with visual impairment and also the Electronic Leaflet, used to facilitate quick access for the population and professionals in the area (Brasil, 2025).

4 CONCLUSION

After reading and interpreting these findings, it was concluded that package inserts are essential in the lives of users and therefore must be clear and easy to interpret to assist in the correct therapy and inform the side effects that it can cause. The correct reading of package inserts can avoid self-medication and irrational use of medications.

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