ClinicSearch

International Journal of Biomed Research

Carminda Maria Bento Martins *

Open Access

Research Article

Implications of Adverse Drug Reaction Reporting in the Stock Management of a Hospital Ambulatory Pharmacy and in Patient Life Quality

Carminda Maria Bento Martins*, Marco António Teixeira Berenguer, Rita da Silva Gonçalves, Dina Vieira

Hospital Pharmacist with the Professional Category of Senior Assessor, Exerting Functions in the Pharmaceutical Services of Centro Hospitalar Universitário do Algarve – Faro Unit, Portugal.

***Corresponding Author:** Carminda Maria Bento Martins, Hospital Pharmacist with the Professional Category of Senior Assessor, Exerting Functions in the Pharmaceutical Services of Centro Hospitalar Universitário do Algarve – Faro Unit, Portugal.

Received date: November 03, 2023; Accepted date: November 29, 2023; Published date: December 06, 2023

Citation: Carminda M. B. Martins, Marco A. T. Berenguer, Rita de S. Gonçalves, Vieira D., (2023), Implications of Adverse Drug Reaction Reporting in the Stock Management of a Hospital Ambulatory Pharmacy and in Patient Life Quality, *International Journal of Biomed Research*. 2(6); **DOI:**10.31579/2834-5029/036

Abstract

The report of an ADR to a drug (generic or original) allows the hospital to initiate a tender for the acquisition of the therapeutic alternative (i.e., another generic drug or even the branded drug with the same active ingredient) which does not cause the reported ADR in the patient. A retrospective study analyzing ADR reports to several drugs with different generics marketed, as well as to brand-name drugs, was conducted. It was found that most of the ADRs reported occurred with generic drugs (mostly with a drug used in the treatment of breast cancer – anastrozole), and these may be related to the formulation of the tablets or to the excipients used, since patients improved the symptomatology presented when changing the commercial brand. It can be concluded that the role of the pharmacist in reporting ADRs to different drugs should be considered of paramount importance, since it would allow the optimization of treatments and consequently the improvement of patient life quality. The implemented measure of acquiring the trademark of the drug best tolerated by the patient implies a rigorous management of stocks.

Keywords: ADR; generic drug; pharmaceutical tendering; life quality

Introduction

The primary goal of drug policy is to assure drug access to all citizens, guaranteeing its effectiveness, safety, and quality, as well as its rational use. Drugs and healthcare products requiring increased vigilance and control, due to is potential toxic cargo, the characteristics of the pathologies for which they were prescribed, and/or their high cost, are usually dispensed by Hospital Pharmaceutical Services (in Portuguese, Services Pharmaceutics Hospitallers (SFH)) of the hospital entities under the National Health Service (in Portuguese, Service Nacional de Saudi (SNS)), according to the terms of the current legislation in place, with the goal of promoting therapeutic adherence and contributing to the improvement of the effectiveness and safety of such drugs. [1]

The Portuguese Administrative Decree No. 210/2018 of March 27 determines the uniformization of the procedures and mechanisms for the monitorization of drugs and health products dispensed by/through SFH, including those destined to be administrated by health care professionals at hospital ambulatory services (day hospital, external appointment, outpatient surgery and emergency service). It also establishes that the prescription and dispense/administration of such drugs and health products are done and registered in electronic systems that allow access to and facilitate communication with data from the Ministry of Health. [1]

Pharmacovigilance aims to improve the safety of drugs, in defence of the patient and Public Health, through the detection, evaluation and prevention of ADR (Adverse Drug Reactions). [2]

The intervention of the pharmacist who directly contacts with the patient on an ambulatory basis is of high importance, since the detection and reporting of adverse drug reactions highly contributes to the improvement of the quality of the treatments instituted and consequently to the improvement of patient life quality.

In Portugal, drugs provided in the context of a hospital ambulatory are mandatorily prescribed according to the International Nonproprietary Names (INN; in Portuguese, Demoniacal Comum International (DCI)), and never by the commercial name of the drug. [3-5] The acquisition of drugs consumed in a hospital environment is made by DCI, though centralized acquisition or via internal tendering of the hospital, with the award criterion being the most economically advantageous proposal. [6, 7] This implies that, in the existence of generic drugs of lower cost, they have to be the ones purchased and used.

According to the Portuguese Decree-Law No. 176/2006 of August 30 [8], in its current wording, the marketing authorization of generic drugs is subject to the same legal provisions as other drugs, and the presentation of pre-clinical and clinical trials is waived, provided that bioequivalence is

demonstrated through bioavailability studies or, when these are not adequate, therapeutic equivalence is demonstrated through appropriate clinical pharmacology studies (these tests strictly follow the provisions of community standards) or others to be requested by INFARMED – Portuguese National Authority for Drugs and Health Products (in Portuguese, INFARMED - Autohidden Nacional do Medicament e Products de Saudi, I.P.).

The report of an ADR to a drug (generic or original) allows the hospital to initiate a tender for the acquisition of the therapeutic alternative (i.e., another generic drug or even the

branded drug with the same active ingredient) which does not cause the reported ADR in the patient. Sometimes, it might be necessary to test more than one alternative to find the drug that does not cause ADR. In its impossibility, it can be concluded that the ADR results from the active ingredient, and in these situations the doctor should change the prescription to a therapeutic equivalent or another drug from a different therapeutic line for the concrete indication.

Objectives

Retrospective study analyzing ADR reports to several drugs with different generics marketed, as well as to brand-name drugs, that occurred in patients followed on an outpatient basis at the hospital ambulatory pharmacy of the Faro Unit of Centro Hospitalar do Algarve, E. P. E., where the study was conducted.

Materials and Methods

Analysis of ADR reported in the 2020, 2021 and April 2022 which occurred in outpatients, being mainly analysed drugs with several generics marketed, given that in these cases the ADRs may be associated with the excipients and formulation of the drug, rather than with the effect of the active ingredient itself.

Evaluation of the type of ADR, as well as the decision taken upon it.

Results

Active Ingredient	Number of reportedADRs
Adalimumab 40mg	4
Anastrozole 1mg	19
Bicalutamide 50 mg	2
Bictegravir 50mg + Emtricitabine 200mg + Tenofovir alafenamide 25mg	5
Capecitabine	1
Dasatinib 100 mg	1
Dolutegravir + Abacavir + Lamivudine, 50 mg + 600 mg + 300 mg	3
Dolutegravir + Lamivudine, 50 mg + 300 mg	1
Eltrombopag 25mg	1
Emtricitabine 200mg + Rilpivirine 25mg + Tenofovir alafenamide 25mg	1
Emtricitabine 200mg + Tenofovir disoproxil 245mg	4
Dimethyl Fumatrate 240mg	4
Imatinib 100 mg	1
Imatinib 400 mg	10
Lenalidomide 25 mg	1
Letrozole 2.5 mg	3
Nilotinib 200mg	2
Olaparib 150mg	1
Osimertinib 80mg	1
Paricalcitol 1mcg	1
Peginterferon beta-1a 125mcg	1
Pirfenidone 801mg	1
Sofosbuvir 400mg + Velpatasvir 100mg + Voxilaprevir 100mg	1
Talidomide 50 mg	1
Tenofovir 245 mg	2

Table 1

	Measure Adopted					
Active Ingredient	**Change to Tamoxifeno**	**Replacementof the laboratorial brand of the drug**	**Graduated glasses**	**Continuedwith no recovery**	**Treatment suspension**	**Total**
Anastrozole 1mg	1	18				19
Bicalutamide 50 mg		1		1		2
Emtricitabine 200mg + Tenofovir disoproxil245mg		1		2	1	4
Imatinib 100 mg		1				1
Imatinib 400 mg		10				10
Letrozole 2.5 mg		2			1	3
Tenofovir 245 mg		1	1			2
Grand Total	**1**	**33**	**1**	**2**	**1**	**41**

Table 2

Discussion

The variability of brands made available depends on budgetary issues, or even on the unavailability of the drug by the laboratory to which it was awarded, which implies the acquisition of the runner-up drug or even the preparation of tenders for a few months.

It was found that most of the ADRs reported occurred with generic drugs (mostly with a drug used in the treatment of breast cancer – anastrozole), and these may be related to the formulation of the tablets or to the excipients used, since patients improved the symptomatology presented when changing the commercial brand of the drug.

The ADRs related to the use of Imatinib should also be noted, since these are mainly related to the type of coating of the tablets, taking into account the complaints submitted by patients and the description of the characteristics of the tablet marketed by Farmoz, where it is stated that the drug has a coating, but for patients who cannot swallow the film-coated tablets, the tablets can be dissolved in a glass of still water or fruit juice. [10]

The implementation of these reports allowed the Pharmaceutical Services to obtain plausible reasons that made it possible to acquire the drugs best tolerated by patients in tendering processes, although they may have higher costs, thus contributing to an improvement in the adherence, and consequently in the effectiveness, of treatment, as well as in the patient's quality of life. These acquisitions of different commercial brands, depending on the response to the treatments presented by the patients in which ADR was reported, require a more rigorous control of stocks, justifying the need to have several trademarks of the same active ingredient.

Conclusions

It can be concluded that the role of the pharmacist in reporting ADRs to different drugs should be considered of paramount importance, since it would allow the optimization of treatments and consequently the improvement of patient life quality.

In accordance with Annex I of Decree-Law No. 176/2006 of August 30 [8], in its current wording (Drug Statute): unless there is adequate justification, the maximum acceptable deviation for the content of the active substance in the finished product must not exceed (more or less) 5% at the time of manufacture.

The implemented measure of acquiring the trademark of the drug best tolerated by the patient implies a rigorous management of stocks in order to comply with this premise.

More detailed studies are needed regarding the composition of drugs and their formulation in order to obtain a causal relationship on the emergence of ADRs to drugs with the same active ingredients but produced and marketed by different laboratories.

References

1. Normas de prescrição e dispensa de medicamentos e produtos de saúde a utentes em regime de ambulatório hospitalar, SNS, ACSS, Infarmed, SPMS.
2. https://www.infarmed.pt/web/infarmed/perguntas-frequentes-area-transversal/medicamentos_uso_humano/farmacovigilancia
3. Despacho n. 13382/2012, Diário da República, 2. série, n. 198.
4. Procedimentos de cedência de medicamentos no ambulatório hospitalar, Circular Normativa INFARMED,
5. Portaria n. 210/2018, Diário da República, 2.ª série,
6. Circular Informativa Conjunta nº 013/2021/INFARMED/ACSS/SPMS.
7. Despacho n. 16206/2013, Diário da República, 2.ª série, n. 242.
8. Decreto-Lei n. 176/2006, Diário da República 1.a série— N. 167—230.
9. Manual de Boas Práticas de Farmácia Hospitalar, Cap B, Colégio da Especialidade em Farmácia Hospitalar, Ordem dos Farmacêuticos, maio de (2019), p. 11 – 12.
10. RCM Imatinib Farmoz 100 mg comprimidos revestidos por pelicula. (2022).