

ADVERSE DRUG REACTION (ADR) NOTIFICATIONS' IMPACT ON PATIENTS FOLLOWED AT AN AMBULATORY CARE PHARMACY UNIT

Abstract Number: 4CPS-120

ATC Code: 4. Historical Research

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Background and Importance

Pharmacovigilance aims to improve drug efficacy and patient's safety through detection, notification and prevention of Adverse Drug Reaction (ADR). The intervention of Ambulatory Care pharmacist, who assists directly the patient, is highly important because, by detecting and notifying ADRs, it will greatly improve patient's treatment and life quality.

In Portugal, Ambulatory Care Pharmacy drugs are mandatorily prescribed by International NonProprietary Name (INN) and never by its commercial denomination. The purchase of hospital pharmaceutical drugs is executed by their INN by centralized purchase procedures or by internal purchase tenders. One of these procedures' award criterion is the most economically advantageous proposal. This fact implies that, in each pathology treatment, hospitals must purchase and use the cheapest drugs, despite being generic or not. However, the ADR notifications allows the Hospital's Pharmacy and Provisioning Services to launch a purchase tender for therapeutic alternatives which don't cause the same ADR notified to the patients. Although, in some cases, it can be necessary to test more than one therapeutic alternative in order to find the most suitable one for the patient. If it's not possible to find it, we can conclude that the notified ADR is caused by the drug's active substance instead of its excipients. In these cases the physician can either choose to change the prescription to a therapeutic equivalent or to another therapeutic line drug approved for the same clinic situation.

Aim and Objectives

Retrospective study to analyze ADR notifications made between 2020 and 2021, in Faro Unit of Ambulatory Care Pharmacy of Centro Hospitalar Universitário do Algarve, E.P.E. The ADRs occurred in patients followed at this Ambulatory Care Pharmacy facilities.

Materials and Methods

ADR notifications analysis occurred between the years 2020 and 2021 (January-September) in patients followed at the Ambulatory Care Pharmacy.

Results

There were 48 ADR notifications between 2020 and September of 2021.

27 of the ADR notified were with generic drugs, which 16 occurred with Anastrozole, 7 with Imatinib, 1 with Bicalutamide, 1 with Emtricitabine/Tenofovir, 1 with Letrozole and 1 with Tenofovir.

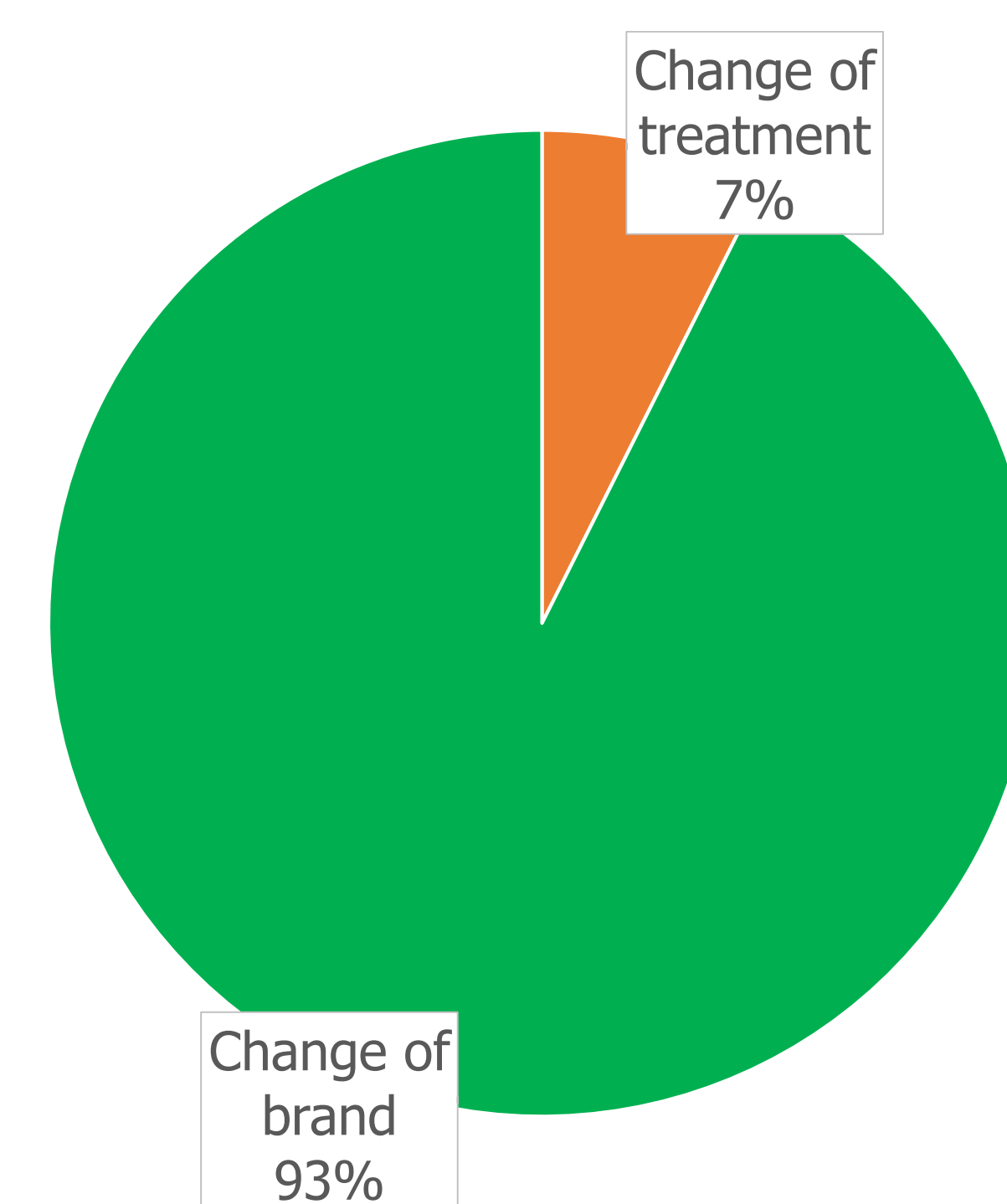
From the total of the ADR related to generic drugs, 93% of the patients changed to another brand of the same drug and 7% had to change their treatment.

To overcome these ADR events, in almost every case, patients were given the same active substances produced by different generic pharmaceutical laboratories. It was also shown that these alternatives were effective in controlling the notified ADR. For almost every patient we switched to the prior generic brand that hadn't caused any ADR event.

Number of reported ADRs and outcomes sorted by drug

Drug by INN	Recovering	Treatment suspension	Change of brand	Persists without recovery	Total
Adalimumab 40mg	1	2			3
Anastrozol 1mg		1	15		16
Bicalutamida 50 mg			1		1
Bictegravir 50mg + Emtricitabina 200mg + Tenofovir alafenamida 25mg	2			1	3
Dasatinib 100 mg	1				1
Dolutegravir + Abacavir + Lamivudina, 50 mg + 600 mg + 300 mg	2				2
Eltrombopag 25mg				1	1
Emtricitabina 200mg + Rilpivirina 25mg + Tenofovir alafenamida 25mg	3				3
Emtricitabina 200mg + Tenofovir disoproxil 245mg			1		1
Fumarato de dimetilo 240mg	2				2
Imatinib 400 mg			7		7
Lenalidomida 25 mg		1			1
Letrozol 2.5 mg		1			1
Nilotinib 150mg				1	1
Peginterferão beta-1a 125mcg				2	2
Sofosbuvir 400mg + Velpatasvir 100mg + Voxilaprevir 100mg				1	1
Talidomida 50 mg		1			1
Tenofovir 245 mg			1		1
Total	11	6	25	6	48

Change of treatment vs Change of brand related to ADRs generic drugs



Conclusion and Relevance

It was verified that the majority of the notified ADR occurred with generic drugs, being most of them associated with Anastrozole, a breast cancer treatment drug, which can be related to the tablet's pharmaceutical formulation or excipients, given that when patients were dispensed a different brand of the same drug, their symptomatology improved. It is also suitable to emphasize that ADRs related to Imatinib were notified, which are fundamentally related to its tablet coating, according to the patients' complaints.

The ADR notifications execution by the pharmacist allowed the Hospital Pharmacy to acquire the best tolerated drugs by the patients, despite the higher costs, contributing for a better patient compliance, treatment efficacy and patient's life quality.

References and/or Acknowledgements

- (1) Despacho nº 4835/2017; Diário da República, 2ª série – nº 107 – 2 de junho de 2017
- (2) Norma Direção Geral da Saúde número 025/2017 de 28/11/2017, atualizada 16/05/2018
- (3) Cit. por Norma DGS 025/2017, p.4