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Dexlansoprazole, lansoprazole: Tubulointerstitial nephritis

Dexlansoprazole is the R-enantiomer of lansoprazole, both substances being proton pump inhibitors (PPIs). When concentrated in the parietal cells of the stomach, they become active in their acidic environment, interfering with the final phase of gastric acid synthesis by inhibiting the enzyme H+/K+ ATPase through binding to its sulfhydryl group. This inhibition is dose-dependent and reversible, covering both basal and stimulated secretion.

As part of the single European assessment of the PSURs for the active substances dexlansoprazole and lansoprazole, the PRAC at EMA concluded that there is at least a possible causal relationship with tubulointerstitial nephritis, which may progress to other forms of kidney damage. Assessment of data (literature and spontaneous ADR reports) including some cases with positive de-challenge (suspension effect) and/or re-challenge (re-exposure effect), led to th conclusion that a plausible mechanism of action exists. Therefore, the SmPCs of medicines with dexlansoprazole or lansoprazole as active substances now contain the following information:

• Section 4.4. Special warning and precautions for use
Renal impairment
Acute tubulointerstitial nephritis (TIN) has been observed in patients taking [*active substance*] and may occur at any point during [*active substance*] therapy (see section 4.8). Acute tubulointerstitial nephritis can progress to renal failure. [*Active substance*] should be discontinued in case of suspected TIN, and appropriate treatment should be promptly initiated..

• Section 4.8. Undesirable effects
Renal and urinary disorders
"Rare": Tubulointerstitial nephritis (with possible progression to renal failure)
Given the data available in the literature comparing some PPIs, and since there is not enough evidence for a class recommendation, the PRAC is reviewing all PPIs at European level, with similar changes having already been recommended for **rabeprazole, omeprazole and esomeprazole/naproxen**.

Ana Sofia Martins, Magda Pedro

Next: posters from the scientific program of the event commemorating the 30th anniversary of INFARMED - **Pharmacovigilance: Involving the Citizen** –, starting in this issue of the Boletim with: perspectives from patient associations, the industry and the National Pharmacovigilance System on reporting of ADRs by patients, and variation in ADR reporting in the pre- versus the post-pandemic period.

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BREAKING THE CODE: PATIENT ASSOCIATIONS' PERSPECTIVES ON ADVERSE DRUG REACTION REPORTING IN PORTUGAL - INTERIM RESULTS

Maria Regina Pereira[1], João Paulo Fernandes[2], Bruno Sepodes[1 3], Márcia Silva[2], Carla Torre[1 3]

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Introduction

Spontaneous reporting is **crucial** in pharmacovigilance, providing **real-world clinical context and enhancing drug safety** monitoring in the after-market authorization stage.

In Portugal, any citizen can report an adverse drug reaction (ADR) **since 2012**. Patient input provides a deeper understanding of ADR impact, including **psychological and daily life effects**, compared to those made by health professionals.

Promoting ADR reporting among the general public is **challenging** due to the diversity of the population and lack of target engagement. Patient Associations (PA) are an **opportunity to boost pharmacovigilance**, since they assume a **privileged position** with patients, making them aware of pharmacovigilance activities and encouraging them to report ADRs.

Objective

The aim of our study was to **assess the perception** of PA about the process of **reporting ADRs** by their members.

Methods

A descriptive cross-sectional study was conducted accordingly to the following diagram

Approved by the Ethics Committe Faculty of Pharmacy University of Lisbon

Designed in Portuguese and pre-tested for content validity by pharmacists with experience in the pharmacovigilance field and also with a Federation of PA

Released on April, 27th and is still accepting answers

Awareness of ADR reporting importance
Reporting channel
Portal RAM

Results

A total of 42 questionnaire responses were collected up to May, 13th. From the respondents, 42.9% (n=18) had more than 500 members.

Regarding their members....

38.1% considered they do not understand the importance of reporting ADRs for medication safety

7.1% assumed they knew it was possible to report an ADR autonomously, without the help of other people

64.3% shown that they do not know where to report if they experience an ADR

69.1% expressed they do not felt comfortable making a reporting electronically

Portal RAM
Notificação de Reações Adversas a Medicamentos

92.9% associations admitted that the members do not know the "Portal RAM"

7.1% have a link to the "Portal RAM" on their website

71.4% strongly agree that their involvement it the future reformulation of the reporting form of the Portal would be important

Which channel they considered to be the **most accessible** for reporting an ADR

35.7%

http://

23.8% **23.8%** **11.9%**

Conclusion

Our findings suggest the need to **increase awareness** among patients about the importance of reporting ADRs and the available channels for doing so. To improve ADR reporting is crucial to ensure that **reporting platforms**, such as the "Portal RAM", are **user-friendly and meet the needs of patients**. **Engaging Patient Associations in** this effort is particularly important, given their **pivotal role** for increasing awareness among patients. By partnering with PA, a reporting system that **empowers patients** could be developed fostering a **reporting culture**. This approach has the potential to **transform the current landscape** of ADR reporting, and ultimately **improve patient safe**.

Literature

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The consumer as a reporter of safety information: the experience of a pharmaceutical company in Portugal

Mariana Vieira[1], Aléxis Sousa[1], Helena Gama[1], Luís Guedes[1]
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INTRODUCTION

The objective of Pharmacovigilance is to promote the safe use of medicines, protecting citizens and Public Health, through the detection, assessment, and prevention of adverse drug reactions. The contribution of citizens is fundamental for the establishment of a robust and effective system[1].

As part of the National Pharmacovigilance System, Marketing Authorization Holders (MAHs) serve as points of contact that citizens can use to report safety information related to medicines.

OBJECTIVES

This study analyzes notifications received directly from consumers in Portugal by a pharmaceutical company between 2017 and 2022.

METHODS

The data was obtained from the safety database used by the pharmaceutical company, encompassing all notifications received from Portugal between January 1, 2017, and December 31, 2022.

For each notification, the following fields were analyzed: 'source of notification', 'notification year', 'gender', 'age group', 'seriousness', 'channel of notification', and 'need for follow-up'.

RESULTS

Out of a total of 923 received notifications, concerning 38 products, 208 originated from consumers. The remaining notifications had the following sources: 310 from healthcare professionals, 241 from literature, 125 from Infarmed, I.P., 30 from studies, and 9 from other sources.

There were 33 consumer notifications in 2017, 39 in 2018, 36 in 2019, 39 in 2020, 27 in 2021, and 34 in 2022 (fig. 1). Out of the mentioned 208, 124 were from female consumers, 80 from male consumers, and 4 from consumers with unknown gender.

Regarding the age range, 67 notifications were related to adults (18-64 years), 56 to the elderly (≥65 years), 15 to children between 2-11 years, 6 to children < 2 years, 6 to teenagers (12-17 years), and 58 to consumers with unknown age.

190 notifications were considered non-serious and 18 were serious.

The notifications were received as follows: 138 via email, 57 via phone, 9 via website/social media, and 4 through personal contact. 127 notifications were marked for follow-up, and the follow-up was successful in 115 cases.

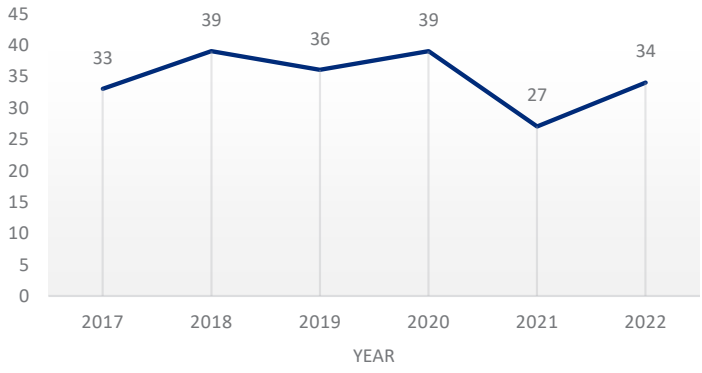
CONCLUSION

In the past 6 years, **22.5% of notifications were received from consumers**, mainly through email (66.3%) or phone (27.4%). Demographically, the female gender (59.6%) and adults (32.2%) stand out. It is worth noting the high proportion (90.6%) of notifications that were successfully followed-up.

In 2021, Infarmed, I.P. received a total of 26,726 direct notifications, of which 4,980 (18.6%) were from consumers [2]. In comparison, out of the 158 notifications received by the pharmaceutical company, 27 (17.1%) were from consumers. **The similarity in percentages may suggest that consumers use both channels for reporting.**

The annual number of notifications received by the pharmaceutical company has remained relatively stable over the analyzed period. Therefore, it's important to **encourage consumer participation**, leveraging their potential to improve drug safety, especially by reporting aspects that healthcare professionals might overlook such as quality of life issues, or by communicating earlier[3].

Figure 1 | Number of Notifications Reported by Consumers in Portugal per Year



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2 INFARMED, Relatório de atividades do Sistema Nacional de Farmacovigilância (SNF) 2021, Publicação Online, acedido em 08/05/2023

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Conflict of Interest Declaration: The authors are employed by Bial - Portela & Cª, S.A.

Summary

Over a 6-year period, a total of 923 notifications were received from Portugal, out of which 208 were from consumers (22.5%).

Marketing Authorization Holders (MAHs) through their communication channels can facilitate and encourage consumer reporting, complementing other existing forms of notification, notably the RAM Portal.

ADR REPORTS IN PORTUGAL: HEALTH PROFESSIONALS VS CONSUMERS
10 YEARS OF EXPERIENCE

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INTRODUCTION

The National Pharmacovigilance System (NPS) was born in 1992 in Portugal. For several years, it only received direct reports of suspected adverse drug reactions (ADR) from healthcare professionals (HCP). As of July 2012, with the transposition of Directive No. 2010/84/EU of the European Parliament and of the Council into national legislation, Portuguese consumers also have the possibility of reporting ADRs. Although there are publications on the added value of consumer participation in ADR reporting, there is little data on ADR reporting in the Portuguese population.

AIM

To characterize the national reports of ADR carried out by consumers since their entry into the National Pharmacovigilance System (NPS) and compare them with the healthcare professionals' reports.

METHODS

Study Design
- Observational
- Retrospective
- 01/2013 a 12/2022 (10 anos)

Sample
- ADR reports
- Direct pathway (Consumers+HCP)

Macro Analysis
- Total of reports
- Seriousness
- Gender and Age (Patient)

Medicines Analysis
- ATC Group*

Anatomical Therapeutic Chemical

ADR Analysis
- System Organ Class*
- Described/Non described**

System Organ Class: higher hierarchical level of MedDRA coding
** Source: Summary of Product Characteristics (SmPC)

Statistical analysis: In the percentage comparison, the Chi2 test was used with a significance level of 0.05; SPSS statistics 28.0®

Note: Each ATC contributed to the count as follows: for each different drug present in each case, 1 ATC was counted.

Note: If in the same report there was more than one adverse reaction belonging to the same MedDRA code (SOC), the code was only counted once.

RESULTS

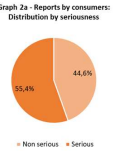
Macro Analysis

Over ten years, 46855 reports of ADR reached the NPS, of which 8104 came from consumers (17% of the total number of reports received directly).

Graph 1 - Number of reports per year: Distribution by reporter group

In this period, there was a very similar proportion of serious reports (HCP: 54% vs Consumers: 55%).

Graph 2a - Reports by consumers: Distribution by seriousness



Graph 2b - Reports by healthcare professionals: Distribution by seriousness

There was a difference in the most frequent seriousness criterion reported:
- "Medically important condition" (47%) and "incapacity" (45%) in consumers;
- "Medically important condition " (66%) and "hospitalization" (15%) in HCP.

Patient

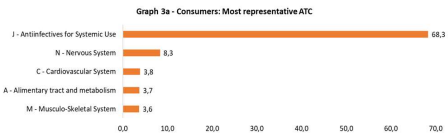
In both types of reporters, most reports are from female patients (64.5% in HCP; 69.5% in consumers).

The age group from 18 to 64 years is the most reported in both types of reporters (66.4% in HCP; 77.7% in consumers).

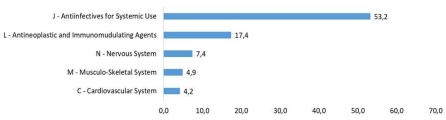
Medicines Analysis

As for the analysis of the drugs involved, when comparing the 5 most reported ATC groups, it appears that 4 were common to consumers and HCP reports, although in different proportions. Consumers mainly reported cases where the suspected drug belongs to the anti-infective (68.3%) and nervous (8.3%) ATC groups.

Graph 3a - Consumers: Most representative ATC



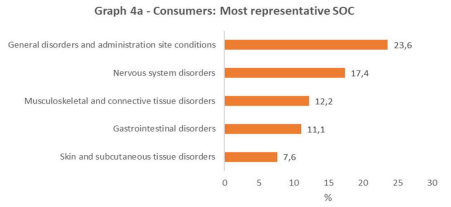
Graph 3b - Healthcare professionals: Most representative ATC



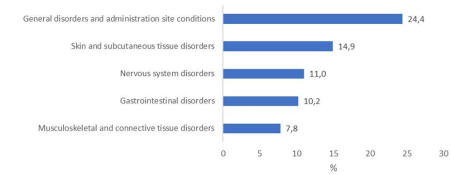
ADR Analysis

Regarding ADR, the most representative SOC groups were common in both types of notifiers.

Graph 4a - Consumers: Most representative SOC

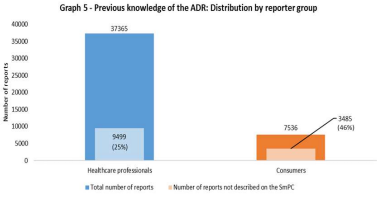


Graph 4b - Healthcare professionals: Most representative SOC



As for prior knowledge of ADRs in the SmPC, it was found that the proportion of reports containing at least 1 ADR not described was higher in the consumer group.

Graph 5 - Previous knowledge of the ADR: Distribution by reporter group



Note: Consumers report a significantly higher proportion of reports whose ADR is not described in the SmPC ($p<0.001$).

DISCUSSION / CONCLUSION

Overall, the evidence shows that reporting by consumers is on the rise. The information arising from consumers' reports is relevant in contributing new information, reporting adverse reactions not yet described in the SmPC, or in relation to the report's seriousness since they specify more clearly how the ADR affected the quality of the patient's life. In this sense, this study suggests that the participation of consumers adds value to health. The national data collected may also make it possible to identify benchmarks that contribute to leveraging the improvement of the SNF, with an ever-increasing participation of citizens. Adverse reactions resulting from vaccination against COVID-19 demonstrated that reporting is accessible to HCP and consumers. In this way, taking advantage of this global awareness is essential to create a commitment among all NPS stakeholders, especially engaging citizens more and more.

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PATIENT INVOLVEMENT IN PHARMACOVIGILANCE: analysis of spontaneous reporting in PRE- AND POST-PANDEMIC PERIOD

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FACULDADE DE FARMÁCIA DA UNIVERSIDADE DE LISBOA

INTRODUCTION

Pharmacovigilance is the science and activities related to the detection, evaluation, understanding and prevention of adverse drug reactions (ADR) or any other drug-related problems. This activity allows the monitoring of the safety profile of drugs after they are marketed, through the analysis and evaluation of safety data collected from important sources of information, among which spontaneous reporting stands out. (1)

Spontaneous reporting was the first method created with this purpose, allows the monitoring of all marketed drugs, throughout their entire life cycle, in large populations and with reduced costs. It promotes signals early detection of unexpected, rare, or serious ADR. (2)

In Portugal, Pharmacovigilance activity began in 1992 with the creation of the National Pharmacovigilance System and spontaneous reporting became possible for healthcare professionals (clinicians, pharmacists and nurses). In 2012, the implementation of new European legislation made it possible for citizen/patient to report. Since then, the importance of the contribution of the citizen/patient as a reporter has become evident, as it provides a detailed ADR characterization, with clinical information at a similar level as their healthcare professional and an additional perspective on the impact of ADR on daily life. It allows a more comprehensive detection of unexpected adverse reactions, with important impact in signal detection. (3-5)

The Covid-19 pandemic was declared, by the WHO, on 11th March 2020 and the administration of the Covid-19 vaccines began in Portugal in December 2020. The period that followed was unprecedented for Pharmacovigilance worldwide, with a reporting rate never seen before, in which the citizen/patient assumed a preponderant role. The expectation of pharmacovigilance would be that this experience had been able to create a new culture of reporting among healthcare professionals and citizens.

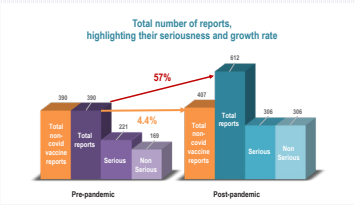
METHODOLOGY

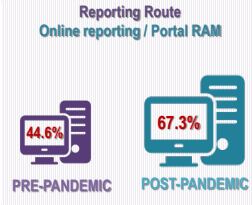
AIMS: Analysis and comparison of spontaneous reporting by patient in the pre-pandemic and post-pandemic period in Portugal.

METHODS: Cross-sectional descriptive study to characterize and compare patient spontaneous reporting, in Portugal, over 2 periods of 1 year, from April 1, 2019 to April 1, 2020 and from April 1, 2022 to April 1,2023, with regard to the total number of reports submitted, the profile of the patient (sex, age group), of the suspected drugs (ATC) and the nature and seriousness of the ADR (MedDRA SOC and PT).

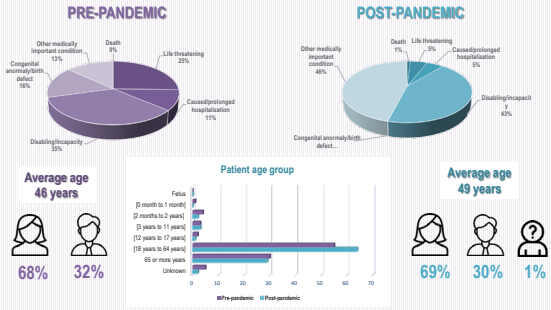
RESULTS

In the 1-year pre-pandemic period analyzed in this study, 390 reports were received from citizens, 44.6% through the online Portal RAM, 57% of which were serious. In the post-pandemic period, 612 reports were received from patients, 67.3% through the Portal RAM and 50% serious, which apparently reveals a growth of 57%. However, if we subtract the remaining reports associated with vaccines against Covid-19 boosters, we find a growth of only 4.4%.





In the pre-pandemic period, the most marked seriousness criteria was "disability/incapacity" with 35% of the total of serious reports, while in the post-pandemic period the criteria "other medically important condition" was the most marked, with 46%. The patient most affected by all the reported reactions was, in both periods, adult women and the patient age group more predominant was adult.

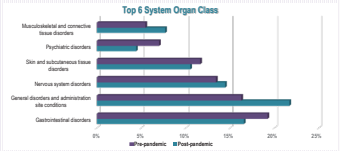


Nausea, Dizziness and Diarrhoea were the most relevant PT terms reported in the pre-pandemic period. Headache, Dizziness and Nausea were the most frequently PT terms reported in the post-pandemic period.

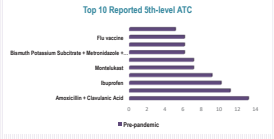
Pre-pandemic	TOP 10 MedDRA PT terms	
MedDRA PT terms	Nausea	32
	Dizziness	31
	Diarrhoea	28
	Vomiting	28
	Headache	27
	Pruritus	24
	Erythema	21
	Malaise	21
	Fatigue	19
	Myalgia	18
	Total	249

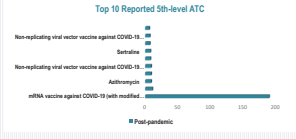
Post pandemic	TOP 10 MedDRA PT terms	
MedDRA PT terms	Headache	81
	Dizziness	63
	Nausea	55
	Myalgia	54
	Fatigue	53
	Diarrhoea	42
	Arthralgia	40
	Malaise	40
	Pyrexia	40
	Asthenia	36
	Total	504

The MedDRA SOC Gastrointestinal disorders, General disorders and administration site conditions, Nervous system disorders, Skin and subcutaneous tissue disorders, Psychiatric disorders and Musculoskeletal and connective tissue disorders were the most relevant in both periods. The SOC most frequently reported in pre-pandemic period was Gastrointestinal disorders and the most relevant SOC in post-pandemic period was General disorders and administration site conditions.



The 5th-level ATC most associated with ADR in the pre-pandemic period was Amoxicillin + clavulanic acid, while in the post-pandemic period it was the mRNA vaccine against COVID-19 (with modified nucleoside).





CONCLUSIONS

Despite the enormous expectation that the period of the Pandemic and the consequent vaccination against Covid-19 could allow for greater involvement of patients in the ADR reporting, the results of this study do not seem to confirm this. Even so, it was possible to identify a positive aspect, the post-pandemic patient seems to be presenting a different profile, being more user of online reporting.

In order to obtain a more robust and less subject to bias comparison, it is suggested to replicate the present study comparing the pre-pandemic period with a post-pandemic period further away from the administration of vaccines against COVID-19

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Certolizumab pegol *Cimzia*	**Patients**	Card 17-05-2023
Dienogest + Etinilestradiol *Eubelle*	**Physicians:** gynaecologists, general/family medicine physicians, dermatologists **Patients**	Checklist Information card 05-06-2023
Emicizumab *Hemlibra*	**Healthcare professionals:** Immuno-haemotherapists who treat patients with haemophillia or, in exceptional cases, haematologists who are expected to prescribe this product. Heads of emergency and nursing services at congenital coagulopathy reference treatment centres. **Lab professionals:** at congenital coagulopathy reference treatment centres **Patients**	Guide Guide Guide for patients/caregivers Patient's card 20-05-2023
Fentanyl *Actiq, lozenges*	**Physicians:** at (chronic) pain and palliative care units; oncologists **Pharmacists** **Patients**	Guide Guide Patient/caregiver guide 09-06-2023
Fingolimod *Fingolimod Accord*	**Physicians:** neurologists and neuropaediatricians **Patients**	Checklist Patient, parents and caregivers guide Pregnancy specific alert card 15-05-2023
Lutetium (177Lu) vipivotide tetraxetane *Pluvicto*	**Patients**	Guide 25-05-2023
Trastuzumab deruxtecan *Enhertu*	**Physicians:** oncologists **Nurses:** oncology **Pharmacists:** hospital	Healthcare professional guide on prevention of medication errors resulting from confusion between medications Healthcare professional guide (pulmonary disease/pneumonitis) 17-05-2023

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Educational Materials published on the Infomed product information webpage

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INN Medicinal product	Target	Materials Online publication date
Treprostinil *Treprostinilo Tillomed*	**Healthcare professionals:** Heads of departments and corresponding physicians from the specialties of cardiology, pneumology, rheumatology, internal medicine, intensive care medicine, and general surgery; head nurses of the above departments; heads of hospital pharmaceutical services	Healthcare professional training on minimization of risks of catheter-related blood stream infections and sepsis Form: "Event of Special Interest – blood borne infection associated with IV treprostinilo Tillomed "
	Patients	Information guide Questionnaire 21-06-2023
Upadacitinib *Rinvoq*	**Physicians:** rheumatologists, internists, dermatologists, immunoallergy specialists, gastroenterologists	Guide
	Patients	Card 27-05-2023

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Communications to Healthcare Professionals published on the Infomed product information webpage

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INN Medicinal product	Target	Materials Online publication date
Ciprofloxacin, Delafloxacin, Levofloxacin, Moxifloxacin, Norfloxacin, Ofloxacin, Prulifloxacina *(systemic - oral and injetable - and inhalation formulations)*	**Physicians:** cardiothoracic surgery, general surgery, maxillo-facial surgery, paediatric surgery, plastic and reconstructive surgery, dermatology, infectious diseases, stomatology, gynaecology/obstetrics, implantology, dentistry, general/family medicine, intensive medicine, internal medicine, tropical medicine, nephrology, neurosurgery, neurology, orthopaedics, ENT, pneumology, urology **Pharmacists:** community and hospital	Antibiotics containing fluoroquinolones (oral, injetable and inhalational routes) – use restriction reminder 08-06-2023
Crizanlizumab *Adakveo*	**Physicians:** haematologists and paediatricians **Pharmacists:** hospital pharmacy services	Withdrawal of marketing authorizatiom within the EU due to lack of therapeutic efficacy 15-06-2023
Pralsetinib *Gavreto*	**Physicians:** oncology and pneumology; heads of department **Pharmacists:** heads of pharmacy services in hospitals treating lung cancer	Increased risk of tuberculosis and minimization measures 16-06-2023
Vosoritida *Voxzogo*	**Healthcare professionals:** multidisciplinary congenital bone dysplasia treatment team: physicians (paediatric endocrinologists, geneticists, paediatricians, paediatric and other orthopaedic surgeons), nurses, pharmacists, and other healthcare professionals	Change in the administration syringe and needle: unit (U) instead of ml 26-06-2023

Compiled by Patrícia Catalão

What do they mean?

ADR	Adverse Drug Reaction
EMA	European Medicines Agency
MA	Marketing Authorization
PL	Patient Information Leaflet
PRAC	Pharmacovigilance Risk Assessment Committee (EMA)
SmPC	Summary of Product Characteristics