FARMACOVIGILANZA
e SICUREZZA *di* FARMACI
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ADVERSE DRUG REACTION REPORTING IN CALABRIA ACROSS THE PERIOD 2011-2016: WHICH IMPACT BY THE NEW EUROPEAN PHARMACOVIGILANCE LEGISLATION?

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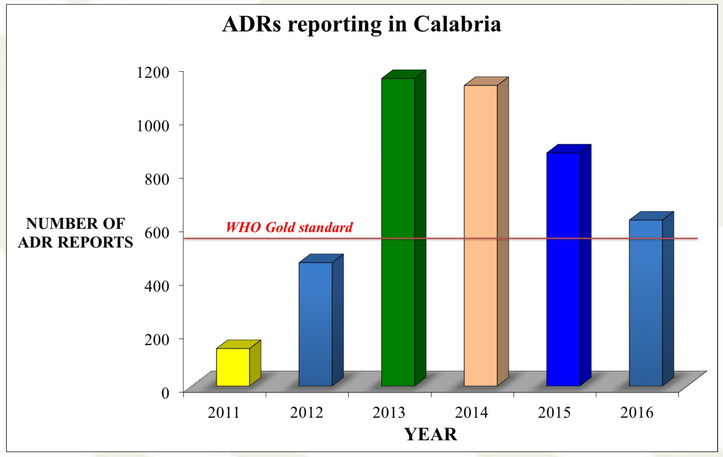
INTRODUCTION

Adverse drug reactions (ADRs) significantly impact clinical practice. In the past few years, a large body of evidence documented that approximately 197000 deaths/year in the European Union (EU) were due to ADRs, resulting in a total cost to the society of about € 79 billions/year [1]. Consistently, some regulatory actions such as rofecoxib withdrawal (2004) or the suspension of the marketing authorization of rosiglitazone (2010) highlighted several weaknesses in the pharmacovigilance legislation. Therefore, an improvement of the entire pharmacovigilance system became necessary. In December 2010, the European Parliament and the Council adopted new pharmacovigilance legislation, which has been effective since July 2012: Directive 2010/84/EU and Regulation (EU) 1235/2010 [2,3]. Such a reform was essentially targeted to optimize pharmacovigilance activities to protect public health by reducing the number and seriousness of ADRs. In line with the EudraVigilance data, the number of suspected ADRs yearly submitted to the Italian Network of Pharmacovigilance (RNF) has progressively increased since July 2012. These results have mostly reflected the agreements between Italian Medicines Agency (AIFA) and Italian Regions, enabling the implementation of active pharmacovigilance projects. Calabria Region (Southern Italy) has carried out an AIFA-funded project since the end of 2010 to increase regional ADR reporting and promote a safer medicines' use. In this study, we investigated the trend of ADRs reporting in Calabria in the period 2011-2016 in light of the above regional project, also trying to analyze the possible entailments of entering into force the new EU Pharmacovigilance rules.

BACKGROUND

The RNF database was electronically searched for all ADR reports (unsolicited and solicited reports) submitted by Calabrian healthcare professionals and patients between 2011 and 2016. A total of 4364 reports were stored in the database in the study period. The retrieved reports were studied by a descriptive analysis including submitting health facilities, reporting sources, ADRs occurrence stratified by age range and gender, ADRs seriousness and outcomes, therapeutic subgroups and active substances involved in ADR reports.



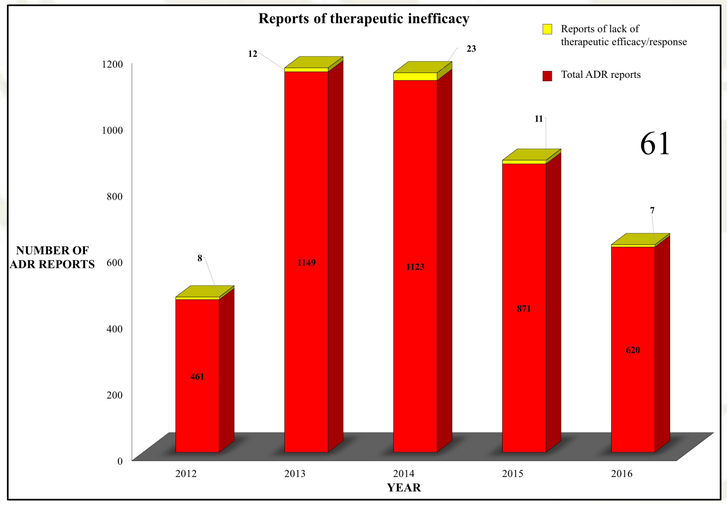
Calabrian trend of ADRs reporting in the study period

RESULTS

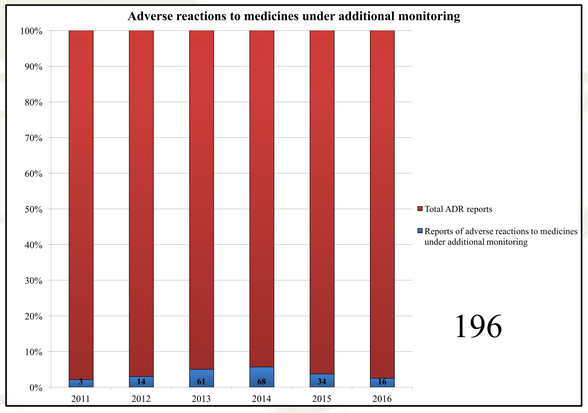
A sharp rise in regional reporting rate was observed in the period 2011-2014. Calabrian Pharmacovigilance system completely fulfilled the World Health Organization (WHO) gold standard for ADR reporting rate (300 ADR reports/1 million people), both in 2013 (581 ADR reports per million of inhabitants) and 2014 (568 ADR reports per million of inhabitants). In contrast to the triennium 2011-2013, the analysis of the period 2014-2016 highlighted a progressive decline in the number of ADR reports (from 1123 to 620), although the regional reporting rate steadily exceeded the annual reporting standard set by the WHO in each year considered. Overall, the improvement of regional ADR reporting was mainly due to the contribution by hospital physicians, specialists, pharmacists, and general practitioners. However, heterogeneity was observed in the reporting behavior of both health facilities and specific stakeholders (patients/citizens and nurses) among the study years.

CONCLUSIONS

These findings reflect the success of the project performed in Calabria. The general improvement of Calabrian pharmacovigilance system exemplifies, in some way, the benefits of the new EU Pharmacovigilance legislation, as observed at national level. However, the regional plan of active pharmacovigilance should go on in the next future to promote a more homogeneous reporting behavior, enabling better and steadier results in the long term.



Reports of lack of therapeutic efficacy/response in the study period



Trend of reporting of adverse reactions to medicines under additional monitoring in the study period

Reports of ADRs from uses outside the terms of marketing authorization, medication errors, occupational exposure, and drug-drug interactions

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Cause	N. reports/2012	N. reports/2013	N. reports/2014	N. reports/2015	N. reports/2016
Abuse	16	34	23	6	2
Off-label use	none	2	4	3	none
Overdose	1	4	4	3	4
Drug-drug interaction	none	4	3	3	none
Occupational exposure	none	none	none	none	none
Medication error	4	1	1	3	none

REFERENCES

1. Commission of the European Communities Staff Working Document (2008).
2. Directive 2010/84/EU of the European Parliament and of the Council (2010). Official Journal of the European Union, 74-99.
3. Regulation (EU) No 1235/2010 of the European Parliament and of the Council (2010). Official Journal of the European Union, 1-16.