22ND CONGRESS OF THE EAHP
"HOSPITAL PHARMACISTS - CATALYSTS FOR CHANGE"
22ND - 24TH MARCH 2017 | CANNES, FRANCE

IMPACT OF SPANISH PHARMACOVIGILANCE LEGISLATION ON SUSPECTED ADVERSE DRUG REACTIONS REPORTED BY THE HOSPITAL PHARMACY SERVICE

Porta Sánchez A, Mondelo García C, Lema Gándara N, Martín Herranz I

Servicio de Farmacia. Instituto de Investigación Biomédica de A Coruña (INIBIC), Complexo Hospitalario Universitario de A Coruña (CHUAC), Sergas. Universidade da Coruña (UDC). As Xubias, 84. 15006 A Coruña, Spain.

Background

- Spanish pharmacovigilance legislation of human medicines states that healthcare professionals are obliged to report suspected adverse drug reactions (ADRs), giving priority to serious ADRs, unexpected or related to drugs under additional monitoring.

Purpose

- To assess the impact of the Spanish Pharmacovigilance Legislation recommendations on ADR reporting by the hospital pharmacy service (HPS).

Material and methods

Retrospective analysis of the severity of ADRs reported by the HPS and those involving medicinal products under additional monitoring.

Study period: August 2013 to March2016. **Data sources:** database of ADRs reported to Regional Pharmacovigilance Centre, electronic medical records and European list of medicinal products under additional monitoring**. Collected data:** date of spontaneous ADR reports, medical record number, demographic dates, drugs involved and communication of ADRs and severity.

Results

319 suspected ADRs reported by the HPS

Mean patient age → 58 years (range: 9 days – 92 years)

Therapeutic groups mainly involved in ADRs	Percentage (%)
Antineoplastic–immunomodulating	43.9
Systemic anti-infectives	25.1
Nervous system	11.6

75.7% of reports corresponded to serious ADRs and/or drugs on the **European list of medicinal products under additional monitoring**

ADRs severity	
Serious ADRs	67.40%
ADRs which caused hospitalisation	26.50%
ADRs which prolonged hospital stay	9.80%

Drugs mainly involved in ADRs	
Everolimus	14/319
Adalimumab	12/319
Linezolid	12/319
Boceprevir	8/319

17.9% of reported ADRs belonged to the **European list of medicinal products under additional monitoring**:
Abiraterone (7)
Boceprevir (8)
Telaprevir (5)
47.4% of them were serious

46.5% of ADRs were considered serious because of their **importance from a medical point of view**

ADRs were the **cause of death in 1.4% of cases**, **endangered life in 12.1%** of cases and **caused persistent/severe disability in 3.7%**

In 11/319 ADRs in patients under 18 years of age, 8 were considered serious, including 2 cases related to **Immunoglobulin against Neisseria meningitidis group B**

Conclusions

- A high percentage of ADRs reported by the HPS was consistent with the pharmacovigilance legislation, highlighting the number of serious ADRs.
- Reporting of ADRs by the HPS contributes to increased awareness of drug safety, especially those recently marketed.

DI 037