ANALYSIS OF THE MEDICINES UNDER ADDITIONAL MONITORING AUTHORIZED IN THE EUROPEAN UNION FROM 2017 TO 2019

P. Pacheco-López1, C. Fernández-Zamora1, M.A. Carvajal-Sánchez1, S. Clavijos-Bautista1, M.A. Meroño-Saura2, J. Ibañez-Caturla1, P. Torrano-Belmonte1, L. Fructuoso-Gonzalez1, M.D. Nájera-Pérez1, M.A. Meroño-Saura2, J. Ibañez-Caturla1, P. Torrano-Belmonte1, L. Fructuoso-Gonzalez1, M.D. Nájera-Pérez1

Hospital General Universitario Morales Meseguer, Murcia, Spain 1. Hospital Perpetuo Socorro, Cartagena, Spain 2.

AIM AND OBJECTIVES

Analyze the characteristics of the Medicines Under Additional Monitoring (MUAMs- ▼) authorized in the European Union from 2017 until 2019. It was also evaluated whether additional measures should be implemented in the Hospital Pharmacy Services to improve the follow-up of the MUAM.

MATERIAL AND METHODS

- A descriptive analysis of the EMA MUAM list (updated on March 25, 2020)
- Authorizations from 01/01/2017 to 31/12/2019.
- The main limitation of this study is the dynamism of the MUAM list, which is updated monthly.

RESULTS

181 MUAMs

<table>
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<tr>
<th>Year</th>
<th>MUAMs</th>
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<td>2017 (33%)</td>
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<td>2018 (44%)</td>
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<td>2019 (23%)</td>
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- New active substances 113 (62,4%)
- New biologicals 55 (30,4%)
- PASS 8 (4,4%)
- Conditional authorization and exceptional circumstances 4 (2,2%)
- Security restrictions 1 (0,5%)

> 60% of the MUAMs authorized are marketed in Spain, most of which are antineoplastic and immunomodular drugs.

13 notes referring to MUAMs

- safety (30,7%)
- contraindications for use (30,7%)
- restrictions on use (23%)
- informative notes (15,4%)

Only 2 of these notes affect one of the authorized MUAMs from 2017 to 2019; tofacitinib.

CONCLUSION AND RELEVANCE

- The most frequent designation criterion was the new active substance, followed by new biological, PASS and conditional or exceptional authorizations.
- The high number of MUAMs authorized and their special characteristics justify the need to implement a circuit in the Hospital Pharmacy Service that includes: clinical sessions, patient information sheets as well as a wider dissemination of information about restrictions of use and contraindications.

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