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

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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.

Aspects studied

- Criteria for inclusion in the MUAM list
- Year of inclusion and marketing status in Spain
- Post-marketing safety
  - Information notes published by the AEMPS

RESULTS

181 MUAMs	
2017 (33%) 2018 (44%) 2019 (23%)	
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**.

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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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