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

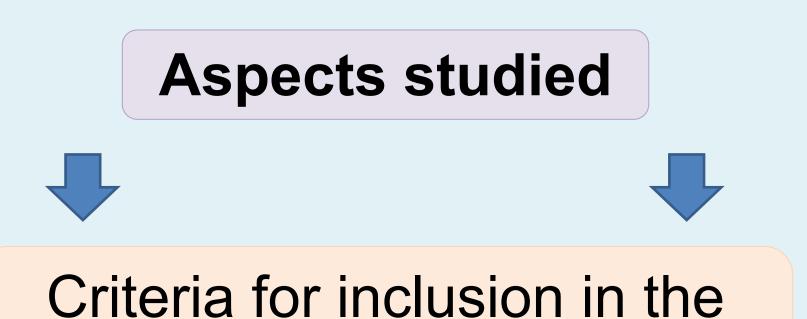
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AIM AND OBJECTIVES Analyze the characteristics of the Medicines Under Additional Monitoring (MUAMs-▼) authorized in the European Union from 2017 until 2019. It was also evaluated whether additional measures should be implemented in the Hospital Pharmacy 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)



	ated on March 25, 2020) orizations from $01/01/2017$ to $31/12/20$	19.	MUAM list	
✓ The r	main limitation of this study is the dyr MUAM list , which is updated monthly	namism	Year of inclusion and marketing status in Spain	Information
	RESU		LTS Post-marketing safety	notes published by the AEMPS
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





> 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.

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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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