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Evolution of Biosimilar Medicines on the Romanian Pharmaceutical Market

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1. Introduction

Biosimilar medicines are authorized through the centralized procedure of the European Medicines Agency (EMA). These products may enter the Romanian market, Romania being a member of the European Union.

In Romania harmonization of law offers the possibility of launching biosimilar medicines. Law 95/2006 contains the definition of biosimilar medicines; Ministerial Order 75/2009 describes the process of price assessment. So, how does a biosimilar product appear on the Romanian market? After the centralized procedure, the National Agency for Medicines and Medical Devices of Romania authorizes marketing and the Healthcare Ministry assesses the price. Government Order 720/2008 approves the list of medicines containing international nonproprietary name (INN) of drugs that patients in the healthcare insurance system benefit with or without personal contribution based on prescription.

2. Materials and methods

This study aims to review the totality of the biosimilar medicines authorized by EMA as well as the products on the Romanian market, and describes the evolution of biosimilar medicines, comparing the number of marketed medicines and active ingredients in 2014, 2017, 2020 and 2021.

3. Results

Figure 2 presents the number of EMA authorized biosimilar medicines on the 9th of October 2021. There are biosimilar products not authorized in Romania. Five biosimilar medicines are missing

from the Romanian market. **Figure 1** presents the EMA authorized products and those existing on the Romanian market between 2014 and 2021.

Table 1 presents the monoclonal antibodies containing products, representing almost half of the authorized products. There are significant differences in the number of commercialized products, for example all products with trastuzumabum and infliximabum existing in Romania, and ranibizumabum lacking totally.

A significant increase of the authorized products may be observed, from 2014 to 2021 a 4.8-fold increase of the number of EMA authorized products, and an almost 6-fold increase of the number of the medicines on the Romanian market. The Romanian healthcare system covers the cost of biosimilar therapy. The price differences of the innovative and the biosimilar medicines varies between 10 to 50%.

4. Conclusions

Biosimilar medicines are available for therapy in Romania. These products open the possibility of modern therapy and enhance the efficiency of the costs in the healthcare system.

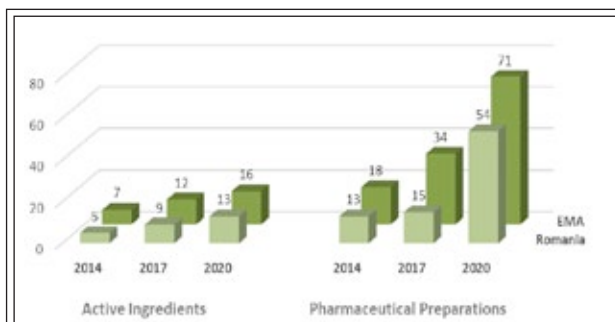


Figure 1 EMA authorized and in Romania commercialized products

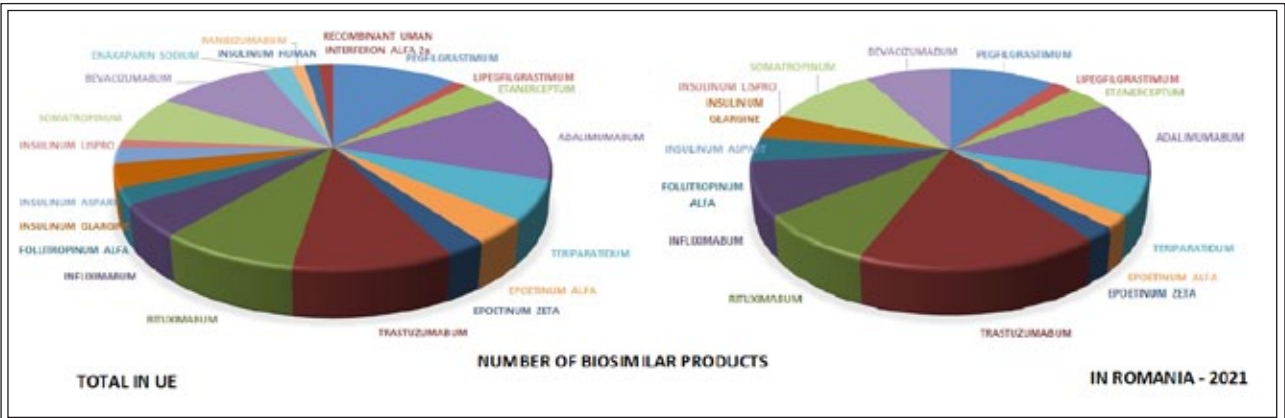


Figure 2 The number of EMA authorized biosimilar medicines on the 9th of October 2021

Table 1 Monoclonal antibodies containing products

Active ingredient	BIOSIMILAR PRODUCTS 2021		Active ingredient	BIOSIMILAR PRODUCTS 2021	
	In Romania	Not existing in Romania		In Romania	Not existing I n Romania
ADALIMUMABUM	Amgevita Hulio Hyrimoz Idacio Imraldi Yuflima	Amsparity Hefiya Halimatoz Kromeya Solymbic	RITUXIMABUM	Blitzima Rixathon Truxima Ruxience	Riximyo Ritemvia Rituzena
BEVACIZUMABUM	Almysys Mvasi Oyavas Zirabev	Aybintio Abevmy Equidacent Onbevzi	TRASTUZUMABUM	Herzuma Kanjinti Ogivri Ontruzant Trazimera Enhertu Kadcyla Zercepac	-
INFLIXIMABUM	Flixabi Inflectra Remsima Zessly	-			

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