TIME TO MARKET AND PRICE COMPARISON FOR BIOSIMILAR DRUGS IN EU5

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INTRODUCTION

- After a medicine receives European Medicines Agency (EMA) marketing authorization, each member state then decides how that medicine is implemented at local level. In Germany, after EMA marketing authorization the drug is available by law. The existing differences between European countries in their policies on biosimilars may explain the heterogeneity in the drug uptake of these biosimilars. As a consequence of these differences, variations in savings can also be observed[1].
- **The aim of this study was to compare the time elapsed from EMA authorisation to national commercialization. Additionally, price differences of biosimilar drugs in five European countries (EU5) were assessed to evaluate whether the existing biosimilar policies might drive this difference.**

METHODS

- Countries included in the analysis were: United Kingdom (UK), Germany, France, Italy and Spain (EU5).
- Authorized biosimilar drugs from April-2006 to January-2018 were extracted from the official EMA's website[2].
- For each country the commercialization of these biosimilars was confirmed via the official websites of the considered National Health Authorities (Agenzia Italiana del Farmaco - AIFA, Agence Nationale de Sécurité du Médicament - ANSM, Gemeinsamer Bundesausschuss – G-BA, Medicines and Health Products Regulatory Agency – MHRA and Agencia Española de Medicamentos y Productos Sanitarios - AEMPS and Consejo General de Colegios Oficiales de Farmacéuticos - CGCOF)[3-9] in May 2018.
- National commercialization dates in each country were collected through the official sources which was the basis for the calculation of median time differences between the EMA authorization and national commercialization date.
- In addition to the median time between EMA approval and national commercialization, the range considering the minimum and maximum time period observed for the different biosimilars evaluated was also calculated.
- Variations in drug prices between the EU5 were also assessed after consulting country-specific official sources[4,8,10-13]. For price comparisons, ex-factory prices were considered (May 2018 €). For Italy and Spain any mandatory low discount has been considered.
- For the price comparison, the package which was available in all EU5 countries was chosen in order to guarantee comparability.

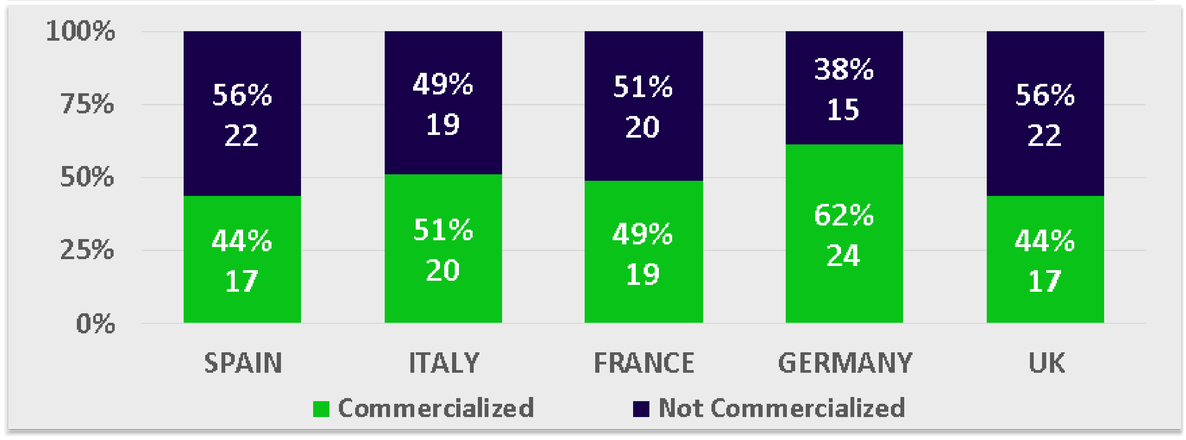
RESULTS

- 39 biosimilars for 15 active substances were authorized by the EMA between April 2006 and January 2018 (Table 1).
- Around 67% (n=26) of the total biosimilars authorized have been commercialized in at least one EU5 country. The overall percentage of commercialized biosimilars ranged from 44% in both UK and Spain to 62% in Germany – in Italy and France the figures were 49% and 51% respectively. In some cases, the existing patents were the reason for the lack of commercialization (i.e. bevacizumab)[14].

Table 1. Biosimilars and their corresponding active substances authorized by the EMA between April 2006 and January 2018

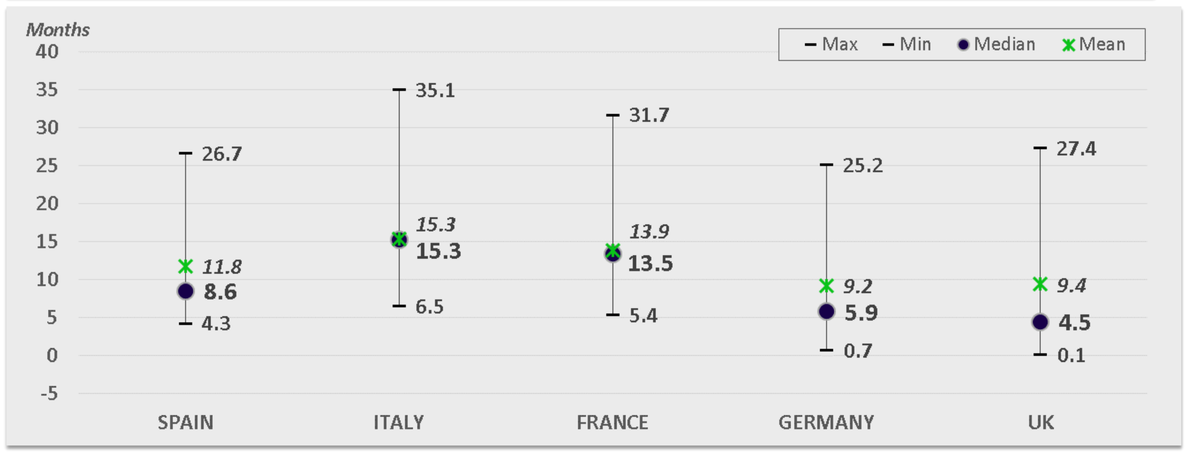
Active substances	Biosimilar brand names	EMA authorization
adalimumab	Amgevita®	22/03/2017
	Solymbic®	22/03/2017
	Imraldi®	24/08/2017
	Cyltezo®	10/11/2017
bevacizumab	Mvasi®	15/01/2018
enoxaparin sodium	Inhixa®	15/09/2016
	Thorinane®	15/09/2016
epoetin alfa	Abseamed®	28/08/2007
	Binocrit®	28/08/2007
	Epoetin Alfa Hexal®	28/08/2007
epoetin zeta	Retacrit®	18/12/2007
	Silapo®	18/12/2007
etanercept	Benepali®	14/01/2016
	Erelzi®	23/06/2017
filgrastim	Ratiograstim®	15/09/2008
	Tevagrastim®	15/09/2008
	Filgrastim Hexal®	06/02/2009
	Zarzio®	06/02/2009
	Nivestim®	08/06/2010
	Grastofil®	18/10/2013
	Accofil®	18/09/2014
follitropin alfa	Ovaleap®	27/09/2013
	Bemfola®	27/03/2014
infliximab	Inflectra®	10/09/2013
	Remsima®	10/09/2013
	Flixabi®	26/05/2016
insulin glargine	Abasaglar® (previously Abasria)®	09/09/2014
	Lusduna®	04/01/2017
insulin lispro	Insulin lispro Sanofi®	19/07/2017
rituximab	Truxima®	17/02/2017
	Rixathon®	15/06/2017
	Riximyo®	15/06/2017
	Blitzima®	13/07/2017
	Ritemvia®	13/07/2017
	Rituzena® (previously Tuxella) ®	13/07/2017
somatropin	Omnitrope®	12/04/2006
teriparatide	Terrosa®	04/01/2017
	Movymia®	11/01/2017
trastuzumab	Ontruzant®	15/11/2017

Figure 1. Biosimilars commercialized in the EU5 countries



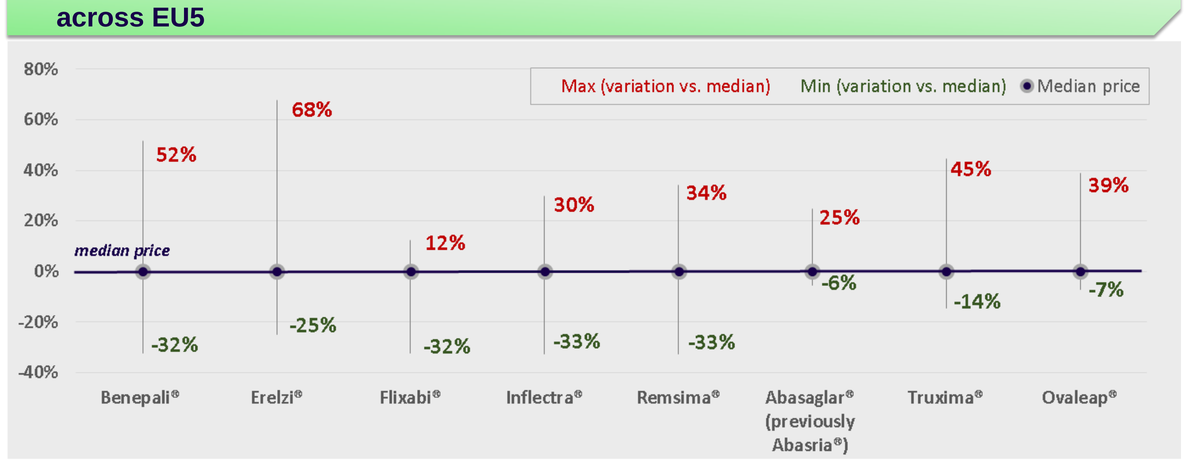
- 36% (n=14) of the authorized biosimilars have been launched in all EU5 countries. Of those, the commercialization date was available for only 9 biosimilars: Abasaglar®, Accofil®, Benepali®, Erelzi®, Flixabi®, Inflectra®, Ovaleap®, Remsima® and Truxima®.
- Of these 9 biosimilars with an available commercialization date in all EU5 countries, the median time elapsed from EMA authorisation to national commercialization was 4.5 months (range 0.1-27.4) in the UK; 5.9 months (range 0.7-25.2) in Germany; 8.6 months (range 4.3-26.7) in Spain; 13.5 months (range 5.4-31.7) in France and 15.3 months (range 6.5-35.1) in Italy.

Figure 2. Time (months) from EMA authorisation to national commercialization across EU5



- Considerable variations on the median price were observed for some of the biosimilars launched in all EU5 countries. For the majority of biosimilars evaluated, and considering the median price observed in the five countries, variations ±25% were observed (Figure 3).
  - ➢ In some countries, the price of Erelzi®, is 68% higher than the EU5 median price, for instance.

Figure 3. Minimum and maximum price variations over the median price observed across EU5



Price information for Accofil® is not shown since the available packs could not be compared and the comparison has been made based on the price per mg.

CONCLUSIONS

- **Biosimilar policies may influence the time to availability of these usually cheaper drugs. Moreover, these policies may impact the prices of biosimilars. For instance, through mandatory price discounts (i.e. in France a mandatory 30% discount vs. the original drug price) or via the competition (i.e. confidential contracting options in Germany).**
- **The joint analysis of the EU5 countries is important in order to understand the differences in market access processes between countries and thus to implement strategies accordingly.**
- **The analysis has considered the EU5 national regulatory systems and variability in access and prices of approved biosimilars in different EU5 countries has been found.**

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