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.
- 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 (EUS) 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 (EUS).
- Authorized biosimilar drugs from April-2006 to January-2018 were extracted from the official EMA’s websites.
- 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) 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 EUS were also assessed after consulting country-specific official sources (EMEA). 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 EUS 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 have been commercialized in at least one EUS 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).

![Figure 1. Biosimilars commercialized in the EUS countries](image)

<table>
<thead>
<tr>
<th>Country</th>
<th>Commercialized</th>
<th>Not Commercialized</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>36%</td>
<td>64%</td>
</tr>
<tr>
<td>Spain</td>
<td>51%</td>
<td>49%</td>
</tr>
<tr>
<td>Germany</td>
<td>62%</td>
<td>38%</td>
</tr>
<tr>
<td>France</td>
<td>49%</td>
<td>51%</td>
</tr>
<tr>
<td>Italy</td>
<td>44%</td>
<td>56%</td>
</tr>
</tbody>
</table>

![Figure 2. Time (months) from EMA authorisation to national commercialization across EUS](image)

- Considerable variations on the price median were observed for some of the biosimilars launched in all EUS 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 Ereliz®, is 68% higher than the EUS median price, for instance.

![Figure 3. Minimum and maximum price variations over the median price observed across EUS](image)

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. 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 EUS 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 EUS national regulatory systems and variability in access and prices of approved biosimilars in different EUS countries has been found.

REFERENCES