# PRICE DIFFERENCES FOR ONCOLOGY DRUGS ACROSS THE EU-5 COUNTRIES: A COMPARATIVE ASSESSMENT

PCN285

Cuesta M[1], Prada M[2], Berard I[3], Vollmer L[4,5] , Guterres S[6]

[1] Oblikue Consulting, Barcelona, Spain; [2] Intexo Srl, Milan, Italy; [3] Nextep, Paris, France; [4] MArS Market Access & Pricing Strategy GmbH, Weil am Rhein, Germany; [5] Applied University of Rottenburg, Rottenburg, Germany; [6] Decideum, London, UK.

## INTRODUCTION

- Pricing and reimbursement decisions after the European marketing authorization are the responsibility of each country, which can lead to inequalities and differences in access and prices for drugs[1] .
- **The aim of this study was to assess market access and price differences in the five European Union countries (EU5) for oncology drugs approved by the European Commission (EC).**

## METHODS

- Countries included in the analysis were: **France, Germany, Italy, Spain and the United Kingdom** (UK).
- **Oncology drugs for which a marketing authorization was granted by the EC centralized procedure between January 2015 and December 2016** were extracted for the analysis from the European Medicines Agency (EMA) website[2].
  - Only initial authorizations were considered.
- **Commercialization status** was confirmed via country-specific health authorities' official websites (Table 1).
  - Oncology drugs that followed an early access pathway (commercialized before receiving the marketing authorization) in France and those that were approved with C-nn class (commercialized even if not yet reimbursed) in Italy were also considered as commercialized.
- The **official ex-factory list prices** were extracted through country-specific official sources (Table 1).
  - National statutory discounts to drug prices were considered in Spain (*Royal Decree-Law 8/2010*[3]) and Italy (*Determinations of July 2006 and September 2006*).
  - In Germany, prices after the early benefit assessment were included.
- **Market access** was analyzed considering the percentage of drugs commercialized at a national level with respect to all oncology drugs approved at EU level.
- In order to have an **anchor price for the comparison**, the country with the lowest expected price, i.e. UK, was chosen to be compared with.

**Table 1. Market access and price data sources in each country**

| Country | Market Access* | Price* |
|---|---|---|
| **Germany** | G-BA[4] | LauerTaxe[5] |
| **France** | French Official Journal[6]<br>ANSM[7] | French Official Journal[6] |
| **Italy** | Italian Official Journal GURI[8] | AIFA[9] |
| **UK** | NICE[10] | MIMS[11] |
| **Spain** | BotPlus[12] | BotPlus[12] |

*Accessed June 2018.

ANSM: Agence Nationale de Sécurité du Médicament et des Produits de Santé; G-BA: Gemeinsamer Bundesausschuss; AIFA: Agenzia Italiana del Farmaco; UK: United Kingdom; NICE: National Institute for Health and Care Excellence; MIMS: Monhly Index of Medical Specialities

## RESULTS

- **26 oncology drugs** were authorized by the EC between January 2015 and December 2016 (Table 2).

**Table 2. Oncology drugs approved by the EC between January 2015 and December 2016**

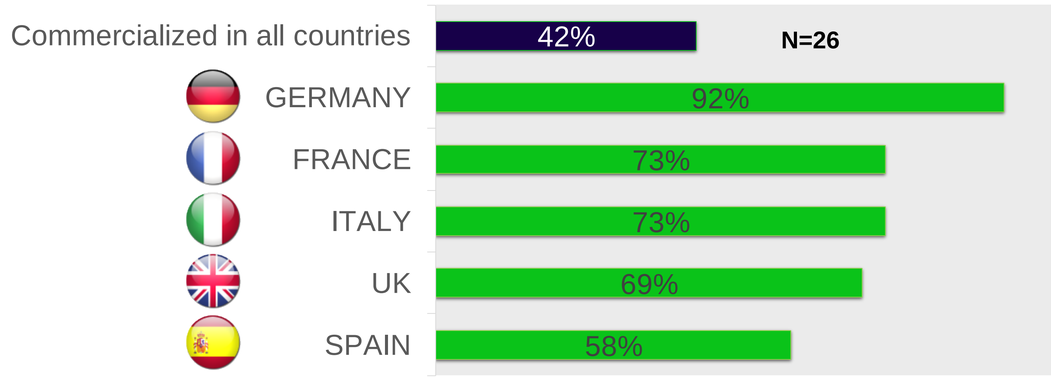
| Brand name | Active substance | European Marketing Authorization date |
|---|---|---|
| Zykadia® | Ceritinib | 06/05/15 |
| Lenvima® | Lenvatinib | 28/05/15 |
| Opdivo® | Nivolumab | 19/06/15 |
| Keytruda® | Pembrolizumab | 17/07/15 |
| Unituxin® | Dinutuximab | 14/08/15 |
| Odomzo® | Sonidegib | 14/08/15 |
| Farydak® | Panobinostat | 28/08/15 |
| Kyprolis® | Carfilzomib | 19/11/15 |
| Cotellic® | Cobimetinib | 20/11/15 |
| Blincyto® | Blinatumomab | 23/11/15 |
| Imlygic® | Talimogene | 16/12/15 |
| Oncaspar® | Pegarspargase | 14/01/16 |
| Spectrila® | Asparaginase | 14/01/16 |
| Tagrisso® | Osimertinib | 02/02/16 |
| Portrazza® | Necitumumab | 15/02/16 |
| Neofordex® | Desametasone | 16/03/16 |
| Lonsurf® | Trifluridine tipiracil | 25/04/16 |
| Empliciti® | Elotuzumab | 11/05/16 |
| Darzalez® | Daratumumab | 20/05/16 |
| Kisplyx® | Lenvatinib | 25/08/16 |
| Cabometyx® | Cabozantinib s-malato | 09/09/16 |
| Onivyde® | Nanoliposomal irinotecan | 14/10/16 |
| Lartruvo® | Olaratumab | 09/11/16 |
| Ibrance® | Palbociclib | 09/11/16 |
| Ninlaro® | Ixazomib | 21/11/16 |
| Venclyxto® | Venetoclax | 05/12/16 |

## RESULTS

### MARKET ACCESS OF ONCOLOGY DRUGS IN THE EU5

- Figure 1 shows the percentage of oncology drugs commercialized at the national level.
  - **Germany was the country with the highest number of oncology drugs commercialized, while the least access was in Spain**.
  - 11 approved oncology drugs have been commercialized in all EU5 countries.
  - 6 out of 18 (32%) commercialized drugs were approved with C-nn class in Italy and 10 out of 19 (53%) drugs were introduced through early access to medicines scheme in France.

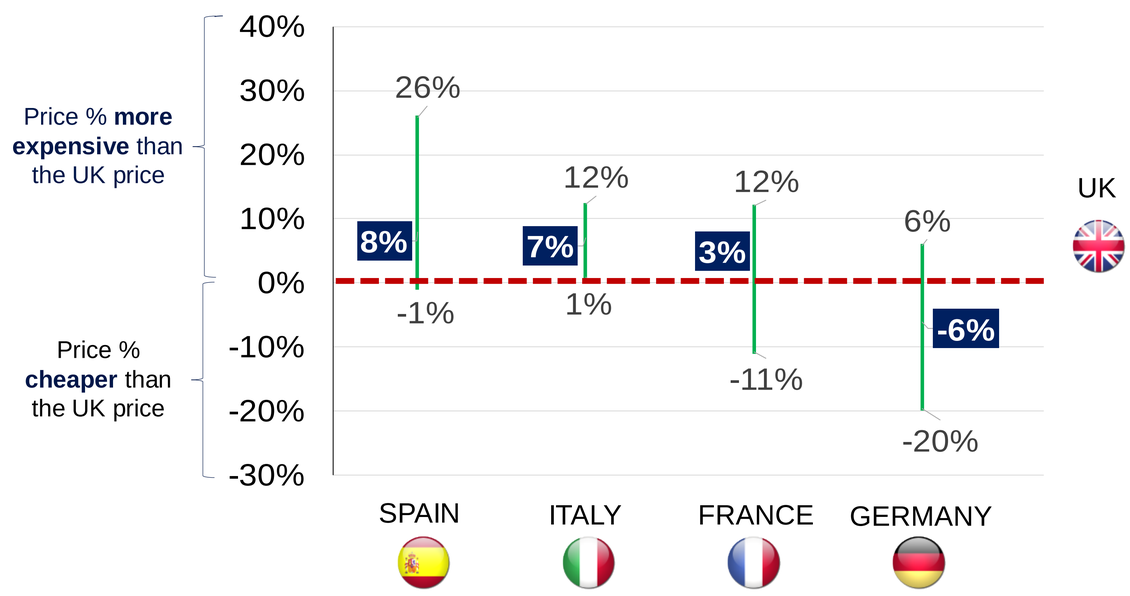
**Figure 1. Oncology drugs commercialized in the EU5**




### PRICE DIFFERENCES OF ONCOLOGY DRUGS IN THE EU5

- Germany, Spain and the UK have publicly-available list prices for all commercialized drugs, while Italy and France have 89% and 74% of drugs with a list price, respectively.
- Compared with the UK, the prices of oncology drugs are higher in Spain, Italy and France. However, the prices after the early benefit assessment are lower in Germany (Figure 2).

**Figure 2. Price differences across the EU5 (median [IQR])**




UK: United Kingdom; IQR: Interquartile Range.

## DISCUSSION

- **Hidden discounts, performance agreement and budget cap** that are increasingly common in Europe are unrevealed[13].
  - The frequency and complexity of confidential negotiations suggests that the **official list prices may not represent the reimbursed price** paid by many institutional payers[13].
- The **joint analysis of EU5 countries** is important in order to understand differences in market access and pricing processes across countries and to implement strategies accordingly.
  - The **transparency** of negotiated prices would allow to perform **better and more realistic price comparisons** across these countries.
- **National/regional budgets and negotiations** in other countries play an important role in **achieving price agreements** at a national level, which delays the availability of new drugs to patients.
- A potential reason for **unknown list prices** of commercialized medicines might be that some drugs were introduced with an **early access to medicines scheme**, in which price and reimbursement are still not negotiated.

## CONCLUSIONS

- **Wide disparity exists in the number of approved drugs available** in each of the European countries since the proportion of oncology drugs commercialized varies from 54% to 92%.
- **More than half of the oncology drugs are still not commercialized** in all the countries.
- The price analysis performed shows that **substantial differences exist across countries**.

[1]Ades F, Senterre C, Zardavas D, et al. An exploratory analysis of the factors leading to delays in cancer drug reimbursement in the European Union: the trastuzumab case. Eur J Cancer. 2014 Dec;50(18):3089-97. [2]European Medicines Agency [Online]. Available at: http://www.ema.europa.eu/ [Accessed 1st June 2018]. [3]Ministerio de Sanidad, Consumo y Bienestar Social [Online]. Available at: https://www.mscbs.gob.es/profesionales/farmacia/pdf/DeduccionesOctubre2018.pdf [Accessed October 2010] [4]Federal Joint-Committee – Gemeinsamer Bundesausschuss (G-BA) [Online]. Available at: https://www.g-ba.de/informationen/nutzenbewertung/ [Accessed 1st June 2018]. [5]Lauer-Fischer GmbH. Lauer-Taxe® [Online]. Available at: https://www.cgm.com/lauer-fischer/index.de.jsp [Accessed 1st June 2018]. [6]Legifrance website. French Official Journal [Online]. Available at: https://www.legifrance.gouv.fr/ [Accessed 1st June 2018]. [7]ANSM. Liste des ATU de cohort [Online]. Available at: ttps://www.ansm.sante.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/ATU-de-cohorte-en-cours/(offset)/2 [Accessed 1st June 2018]. [8]Gazzetta Ufficiale Repubblica Italiana [Online]. Available at: http://www.gazzettaufficiale.it [Accessed 1st June 2018]. [9]AIFA official website. Tabelle Farmaci Classe A e H [Online]. Available at: http://www.aifa.gov.it/content/tabelle-farmaci-di-classe-e-h-al-15052018 [Accessed 22nd June 2018]. [10]NICE [Online]. Available at: https://www.nice.org.uk [Accessed 1st June 2018]. [11]MIMS [Online]. Available at: https://www.mims.co.uk/drugs [Accessed 1st June 2018]. [12]Consejo General de Colegios Oficiales de Farmacéuticos. Bot-PLUS Portal Farma [Online]. Available at: https://botplusweb.portalfarma.com/ [Accessed 1st June 2018]. [13]Morgan SG, Vogler S, Wagner AK. Payers' experiences with confidential pharmaceutical price discounts: A survey of public and statutory health systems in North America, Europe, and Australasia. Health Policy. 2017 Apr;121(4):354-362.

ISPOR 21st Annual European Congress.
10-14 November 2018. Barcelona, Spain.