INTRODUCTION

There are 17 autonomous regions in Spain, which can each make distinct pricing and reimbursement decisions for medicines.

In an effort to introduce more consistency, the Spanish Agency for Medicines and Health Products (AEMPS) has issued national therapeutic positioning reports (TPRs) for new medicines since 2012.

METHODS

All publicly available TPRs were screened up to 31st December 2015 and the date, decision, drug, and indication were extracted.

RESULTS

Frequency

- 67 therapy indications with an associated TPR were identified.
- The number of TPRs issued has substantially increased every subsequent year since 2012 (Figure 1)
  - 1 (1%) issued in 2012
  - 3 (4%) in 2013
  - 10 (15%) in 2014
  - 53 (79%) in 2015.

Therapy Area

- TPRs have been most commonly issued in the oncology space but a wide range of other indications have been covered (Figure 2)
  - 21/67 (31%) were for oncology indications
  - 8/67 (12%) diabetes
  - 7/67 (10%) hepatitis C
  - 6/67 (9%) COPD
  - 6/67 (9%) HIV
  - 4/67 (6%) MS
  - 18/67 (27%) other.

Outcome

- The typical outcome was to be recommended as a possible treatment option, with ‘not recommended’ and ‘superiority’ outcomes being much less common (Figure 3)
  - 14/67 (21%) were deemed to offer superior benefit over existing alternatives
  - 46/67 (69%) were recommended as possible/alternative treatment options
  - 7/67 (10%) were not recommended in any subpopulation.

Economic considerations

- Although economic analyses are not mandatory, recommendations based upon such data were identified in 17 TPRs (Figure 4)
  - Only 4/67 (6%) referenced an economic analysis that affected the overall conclusions
  - 13/67 (19%) referenced an economic analysis that did not affect the overall conclusions
  - Even in instances where an economic analysis was not referenced, a further 25/67 (37%) submissions recommended that efficiency criteria should be considered
  - Efficiency criteria represent the consideration of selecting the therapy of lowest cost where alternatives exist of similar efficacy, safety and convenience

CONCLUSIONS

- The number of TPRs being issued has dramatically increased in 2015, and these reports frequently conclude that a new therapy can be considered as a treatment option but is not superior to currently reimbursed alternatives.
- However, the impact of TPRs has been questioned as they are not mandatory for regions to follow and do not include economic evaluations as standard, a key consideration for regional bodies who are responsible for funding treatments, especially in the current economic climate.