MARKET ACCES IN THE EU, DO WE HAVE ENOUGH EVIDENCE?

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Background

- The EMA is responsible for the scientific evaluation of medicines for use in the European Union, providing a scientific opinion on the granting of EU-wide marketing authorisations.

Purpose

- We conducted a retrospective analysis of new active substances (NAS) that had received positive opinion by the CHMP of the EMA, as well as the authorization conditions and the findings of available therapeutic positioning reports (IPT) published in the AEMPS.

Material and methods

- We analysed NAS with positive opinion from January 2014 until September 17.

- We collected of each NAS the therapeutic area, the type of approval, the route used to, the designation obtained and pivotal trials (according to their design features using the European Public Assessment Reports; in order to evaluate the evidence provided).

- On the other hand, we verified the existence of IPT and analysed its conclusions, as well as the financing conditions. *When a IPT included separate analyses for different indications, we included each separately.

Results

  - 11% were conditional approvals (3:2014, 3:2015, 8:2016)
  - 4 exceptional
  - 15% were carried out by accelerated route
  - 32% were authorized under orphan designation
  - 27% of NAS had at least one Phase-II trial between his pivotal

- Of the 70 existing IPT:
  - only 27% were classified as an advance in therapeutics
  - the majority were classified as similar to alternatives, considering its use based on efficiency criteria
  - 24% were not financed or under conditions by the AEMPS.

Conclusion

- The number of marketing approvals has been a continuing downward trend. However, authorizations with orphan designations and CMA have been increasing. This involved approval with early-stage clinical trials and lack of evidence. In order to avoid uncertainties in decision making, robust evidence must be available from the moment of authorization to facilitate positioning.