HOW A NEW INNOVATION ASSESSMENT TOOL RELATES TO RECENT DRUG LAUNCHES FOR SPANISH NATIONAL ACCESS

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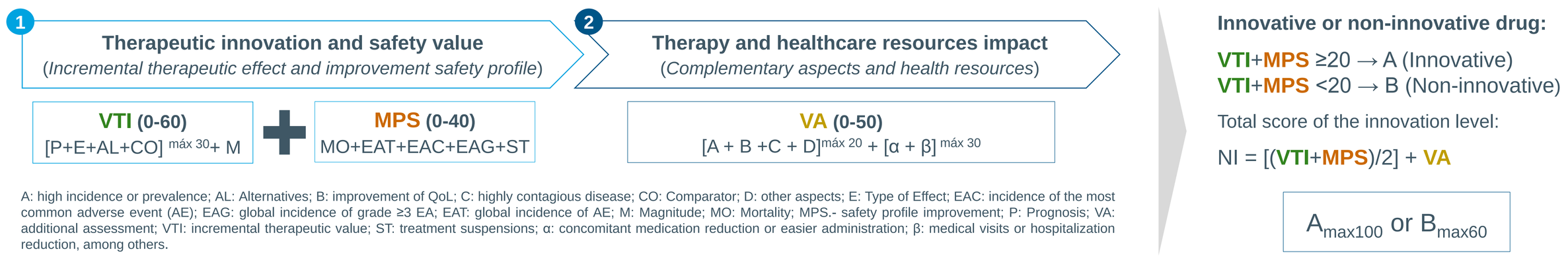
BACKGROUND AND OBJECTIVE

- One of the challenges the Spanish Health System (SHS) is facing is to achieve a balance between the access of innovative health technologies (HT) and the sustainability of the health system. For the inclusion of new HT in the SHS it is important to clearly define the concept of "innovation".
- Recently, the *Dirección General de Cartera Básica de Servicios del Sistema Nacional de Salud y Farmacia* (Ministry of Health, MoH) in collaboration with the Department of Biomedical Sciences of the University of Alcalá (1) have developed a new quantitative tool, known in some areas as "innovómetro", to assess innovation of new HT that could facilitate the pricing and reimbursement (P&R) negotiation and inclusion in the SHS.
- The tool categorizes HT as A (innovative) or B (non-innovative) based on a score that ranges from 0 to 100 depending on efficacy, safety and disease burden, among others (figure 1).
- **The aim of the study was to assess whether this categorization was associated with P&R recommendations, time-to-market and the cost of a selection of drugs.**

METHODS

- Seven researchers independently assessed the level of innovation of drugs with available Spanish therapeutic positioning report (IPT) published between 2015-2017 (2).
- Each drug was independently evaluated by 2 researchers and, in case of disagreement, a third reviewer performed the assessment.
- Drugs were classified by consensus as: A: innovative or B: non-innovative. The final score of each drug was the average score awarded by the 2 researchers who evaluated the drug.
- The following variables were calculated for each group (A and B):
  - The percentage of drugs with positive recommendation and/or indication restriction, obtained from the IPT (2).
  - The time for national access, estimated as the time for P&R in Spain and calculated as the mean (SD) number of days since Spanish Drug Agency (AEMPS) authorization date (3) and Spanish commercialization date (4).
  - The cost, was estimated as the mean (SD) ex-factory price (PVL) (4) per defined daily dose (DDD) (5) in €.

Figure 1. Quantitative algorithm to assess drug innovation.



A: high incidence or prevalence; AL: Alternatives; B: improvement of QoL; C: highly contagious disease; CO: Comparator; D: other aspects; E: Type of Effect; EAC: incidence of the most common adverse event (AE); EAG: global incidence of grade ≥3 EA; EAT: global incidence of AE; M: Magnitude; MO: Mortality; MPS.- safety profile improvement; P: Prognosis; VA: additional assessment; VTI: incremental therapeutic value; ST: treatment suspensions; α: concomitant medication reduction or easier administration; β: medical visits or hospitalization reduction, among others.

RESULTS

- Overall, 37 drugs were evaluated (6), 28 (75.7%) were considered innovative (A) and 9 (24.3%) non-innovative (B), with a mean innovation score of 26.9 and 10.9, respectively.
- Taking into account IPT considerations, all drugs had a positive reimbursement recommendation, although 39.3% of drugs categorized as innovative (A) and 22.2% of non-innovative (B) had a restriction of indication.
- For the overall sample, time-to-market (national access) was estimated at 232.0 days and mean (SD) PVL/DDD was € 285.92 (610.10). Differences in time-to-market and in cost between drugs categorized as innovative (A) and non-innovative (B) are shown in figure 2 and 3, respectively.
- Different trends were observed depending on whether the innovation score was compared with the time-to-market or the drug cost (figure 2 and 3).

Figure 2. Differences in time-to-market between innovative and non-innovative drugs.

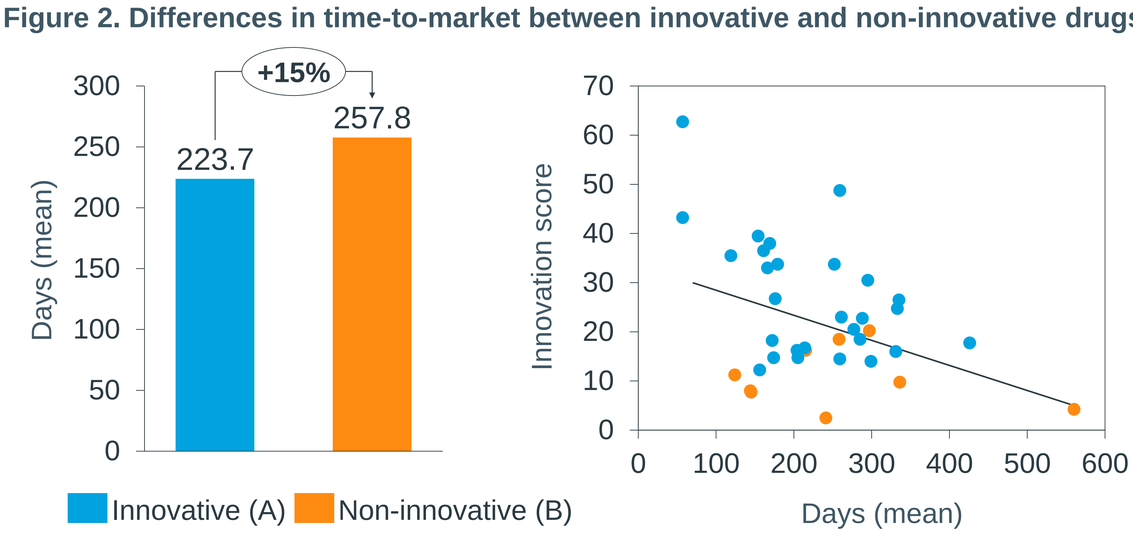
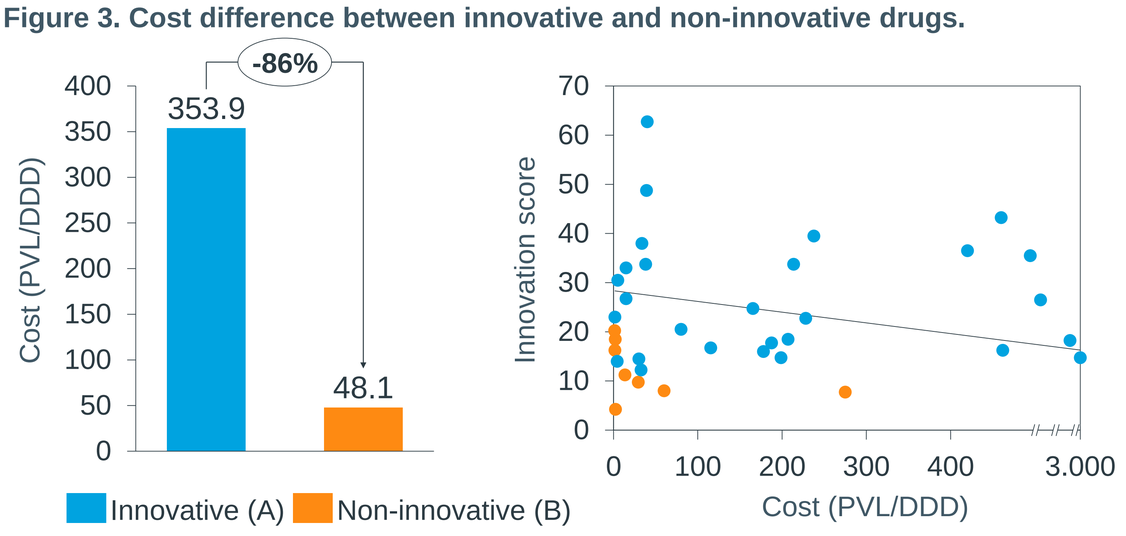


Figure 3. Cost difference between innovative and non-innovative drugs.



CONCLUSIONS

- A higher percentage of innovative drugs (A) showed a restriction of indication in comparison with the non-innovative ones (B), which could be related to the higher cost observed for innovative products.
- The time-to-market was shorter for innovative drugs, but differences were smaller compared to those observed concerning cost per DDD.
- **A new quantitative tool for evaluation of innovation is available in Spain. Although we had a limited sample, innovation categorization seems to be aligned with expectations in terms of indication restriction and cost.**
- **Future research including a higher sample needs to be done in order to provide more clear conclusions.**

(1) Zaragoza F, Cuéllar S., (2017), Innovación y Regulación en Biomedicina: obligados a entenderse. Madrid, España: Fundación Gaspar Casal; (2) Informes de Posicionamiento Terapéutico. AEMPS. Available at: https://www.aemps.gob.es/medicamentosUsoHumano/informesPublicos/home.htm; (3) AEMPS – CIMA. Available at: https://www.aemps.gob.es/cima/publico/home.html; (4) BotPlus. Portalfarma. Available at: https://botplusweb.portalfarma.com/botplus.aspx; (5) WHO – ATC/DDD Index 2018. Available at: https://www.whocc.no/atc_ddd_index/; (6) Los 38 fármacos evaluados con IPT entre 2015-2017 son: Akynzeo, Brimica Genuair, Briviact, Cerdelga, Cosentyx, Cotellic, Cyramza, Darzalex, Duaklir Genuair, Elocta, Entresto, Evotaz, Exviera, Genvoya, Keutruda, Kyprolis, Lenvima, Lonsurf, Lynparza, Mekinist, Moventig, Mysimba, Nucala, Ofev, Opdivo, Otezla, Plegridy, Praluent, Praxbind, Repatha, Sivxtro, Synjardy, Taltz, Viekirax, Xadago, Xydalba, Zepatier y Zerbaxa.

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