

Revalmed: what is the potential impact of this new process on the Spanish market access system?

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Introduction

- The Spanish Agency for Medicines and Health Products (AEMPS) has issued national therapeutic positioning reports (TPRs) for new medicines since 2013. These are comparative efficacy and safety reports which specify the patient population that will benefit most from any new medicine. TPRs were introduced to make access decision-making more transparent and consistent across regions
- In November 2020, Revalmed (Pharmaceutical Evaluation Network) was created to be responsible for a revised process to make TPR development faster and to include pharmacoeconomic evaluations
- The first therapy (talazoparib) evaluated under this new procedure was within a pilot project in June 2021
- This research compares the outcomes of therapies assessed under this new Revalmed process with those not, in the year 2022

Methods

- Publicly-available TPR decisions were identified from www.aemps.gob.es and key information extracted (01-Jan-2022 to 24-Jun-2022)

Results

53 TPRs identified

Revalmed,
21

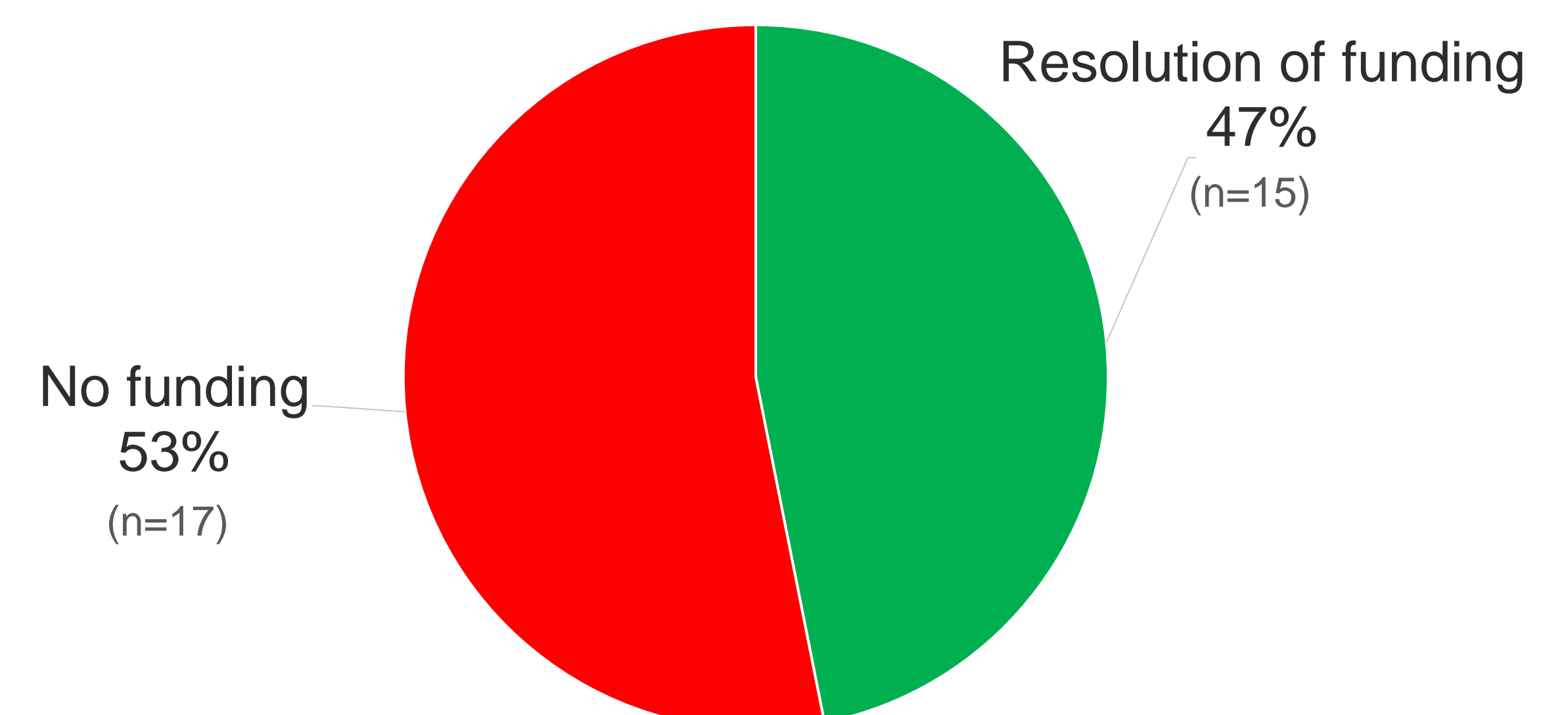
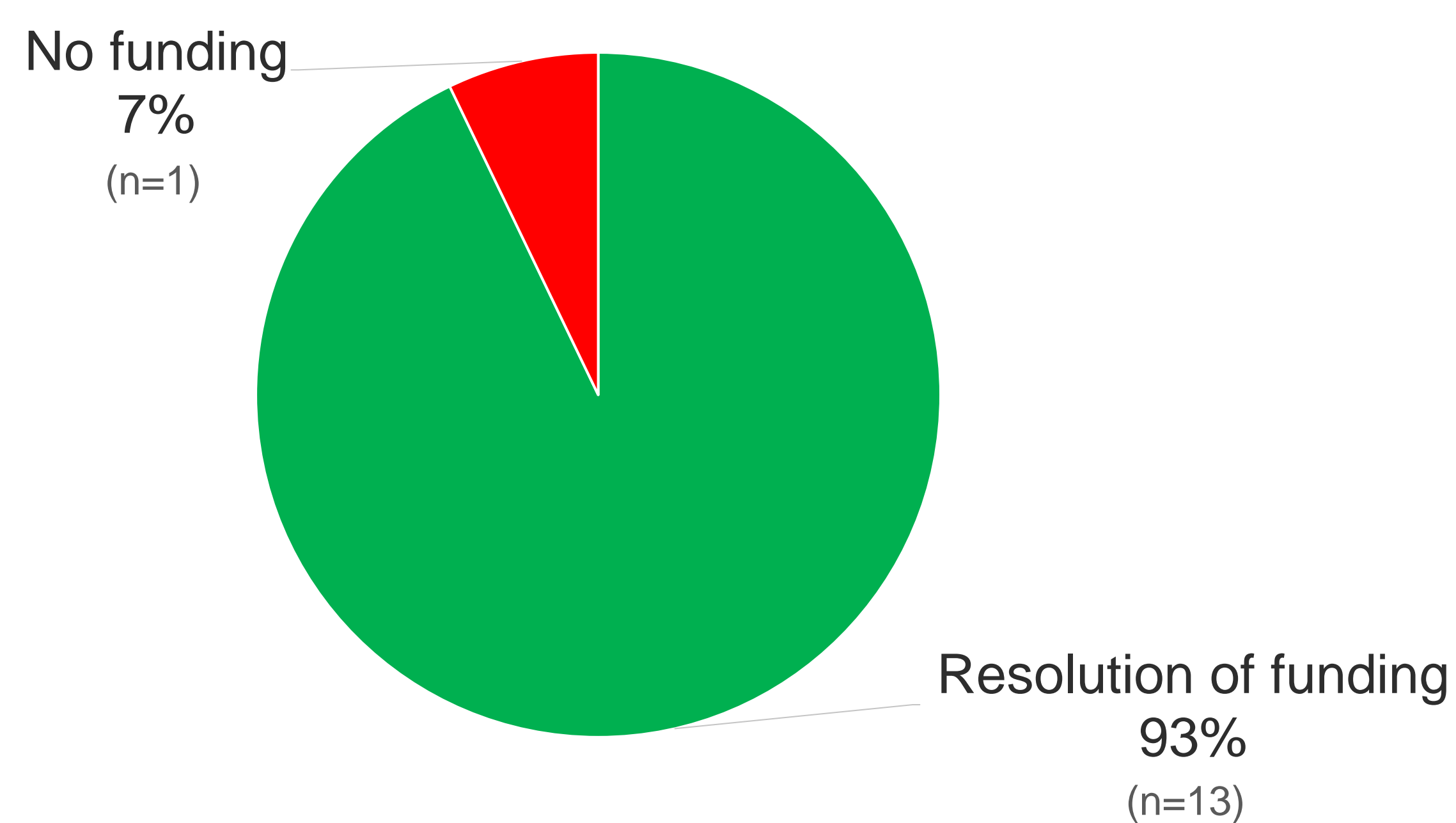
Not
Revalmed,
32

7 TPRs with no
recommendation

Revalmed

Not Revalmed

TPR outcomes, stratified by whether the TPR was evaluated as part of Revalmed or not



Conclusions

- TPRs assessed under the new Revalmed process in 2022 have much more favourable funding outcomes than those that have not been assessed under this pathway
- Further, the potentially increased speed of development of TPRs under this process, combined with inclusion of pharmacoeconomic considerations, may make these TPRs much more impactful in the Spanish national and regional reimbursement process going forward
- Nevertheless, further research is needed to clarify whether this reflects different types of therapies being considered under Revalmed or whether this new process may help support more favourable assessments