



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Parallel Regulatory-HTA Scientific Advice

Health Technology Assessment Network

Results of Pilot

Presented by Jane Moseley on 20 May 2016
Senior Scientific Officer / Scientific Advice

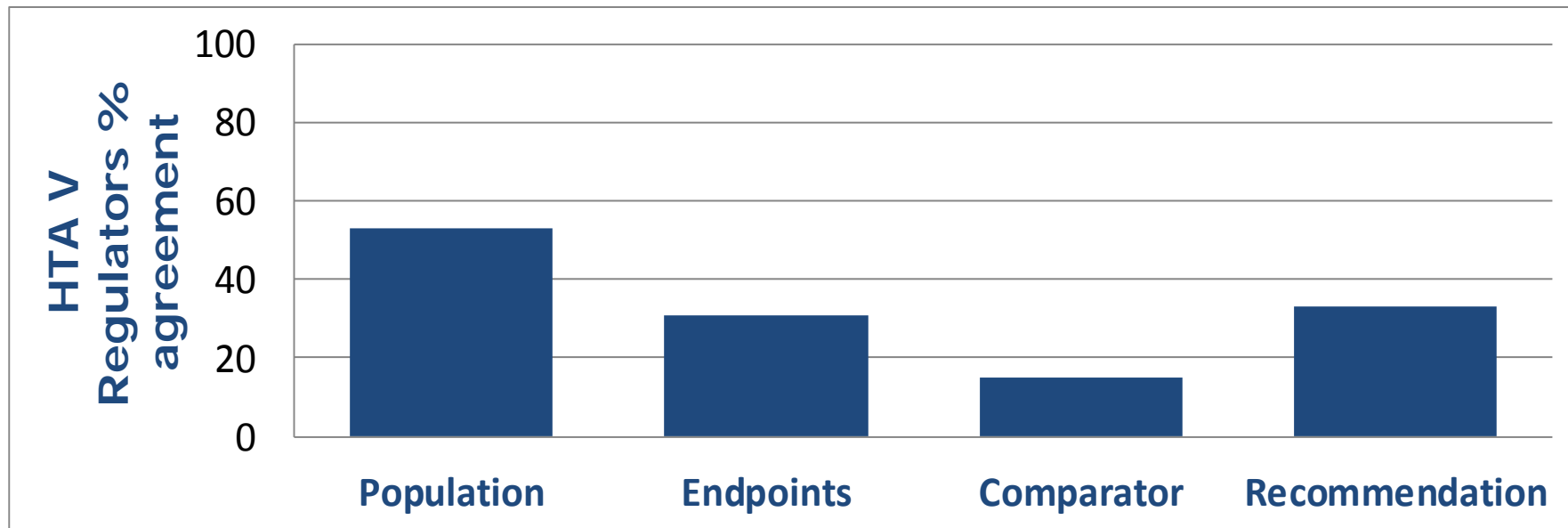
An agency of the European Union





Making the case for parallel advice

56 products

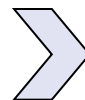


<http://www.efpia.eu/documents/189/61/HTA-Accelerator-In-Depth-Analysis-Final-report>



Why needed?

Exclusion of appropriate comparator



Avoidable issues

Absence of data in a relevant subgroup

Cancer review* - gaps, delays

The Problem

Valid reasons for divergences possible but leads to pressure

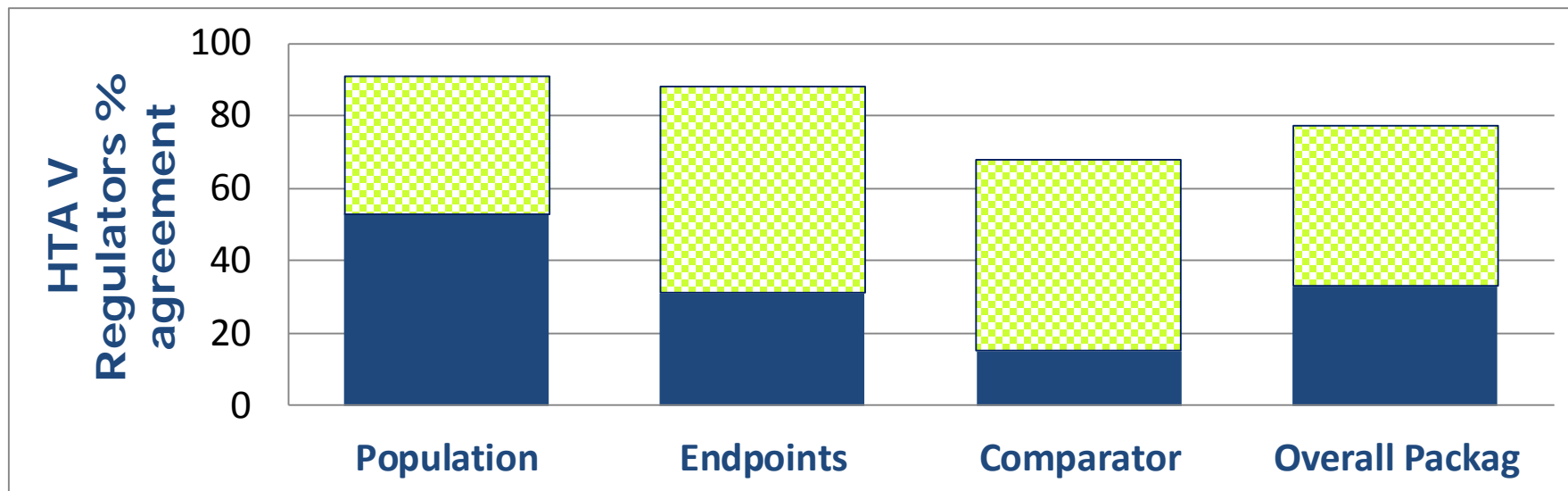
Should be no avoidable reasons based on nature/scope evidence

*Ann [Oncol.](#) 2016 Jan; 27(1):96-105



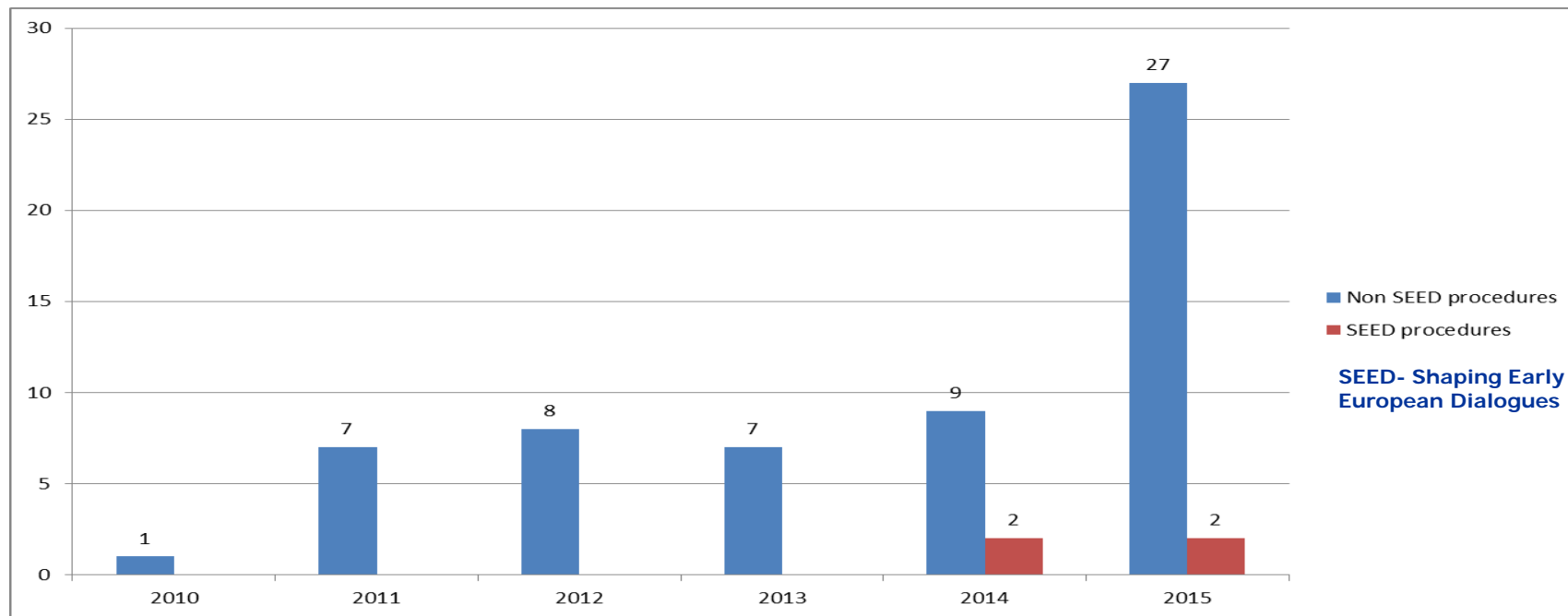
Can Parallel Advice Help?

Reconciled within 1 plan/trial?





What have we learned?



Completed parallel advice procedures / year



What have we learned?

- Public consultation
- Comments and outcomes published
- High level of support
- Constructive changes
- Worked with EUnetHTA/HTAs
- Refined Guidance
- HTAs
 - Lists of issues
 - Written answers
 - Coordinator
 - Closed sessions
- Multi-stakeholder procedure
- One of EUnetHTA collaborative
- Incorporated SEED learnings



Some issues

“Industry applicants select agencies from big markets, ...”

“Simplification of agreements and fees” resourcing?

“A central administrative infrastructure”

- Roles and remits = respected
- Relationship advice and regulatory opinion maker = vital
- Data confidentiality = protected



What have we learned?

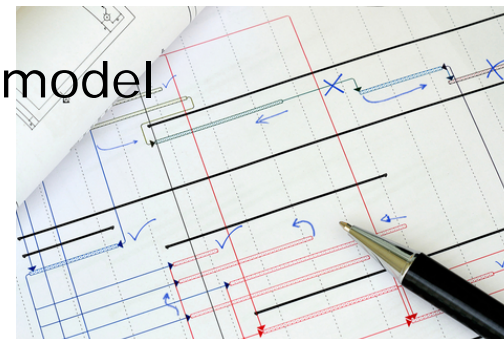


Small Medium Enterprises

- Support and guidance needed

Observations for final model

- Principles
- Processes





Parallel Advice – Regulators and Health Technology Assessment Bodies (HTAs)

- ✓ Pilot concluded– learnings strengths and weaknesses
- ✓ Risk benefit+, now interim phase, future development necessary
- ✓ Collaborative stakeholder interactions on patients' access to new and important medicines
- ✓ Will continue on operational basis
- ✓ EMA willing to work with EUnetHTA & all stakeholders to move forward



Acknowledgements

Steve Cordeiro, Lisbeth Barkholt, Giovanni Tafuri

Thank you for your attention

Further information

Contact me at Jane.moseley@ema.europa.eu

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 7149 **Facsimile** +44 (0)20 3660 5555

Send a question via our website www.ema.europa.eu/contact

Follow us on  [@EMA_News](https://twitter.com/EMA_News)