



Managed Entry Agreements, Coverage with Evidence Development and MCDA: Nice 'buzzwords' vs reality in CEE

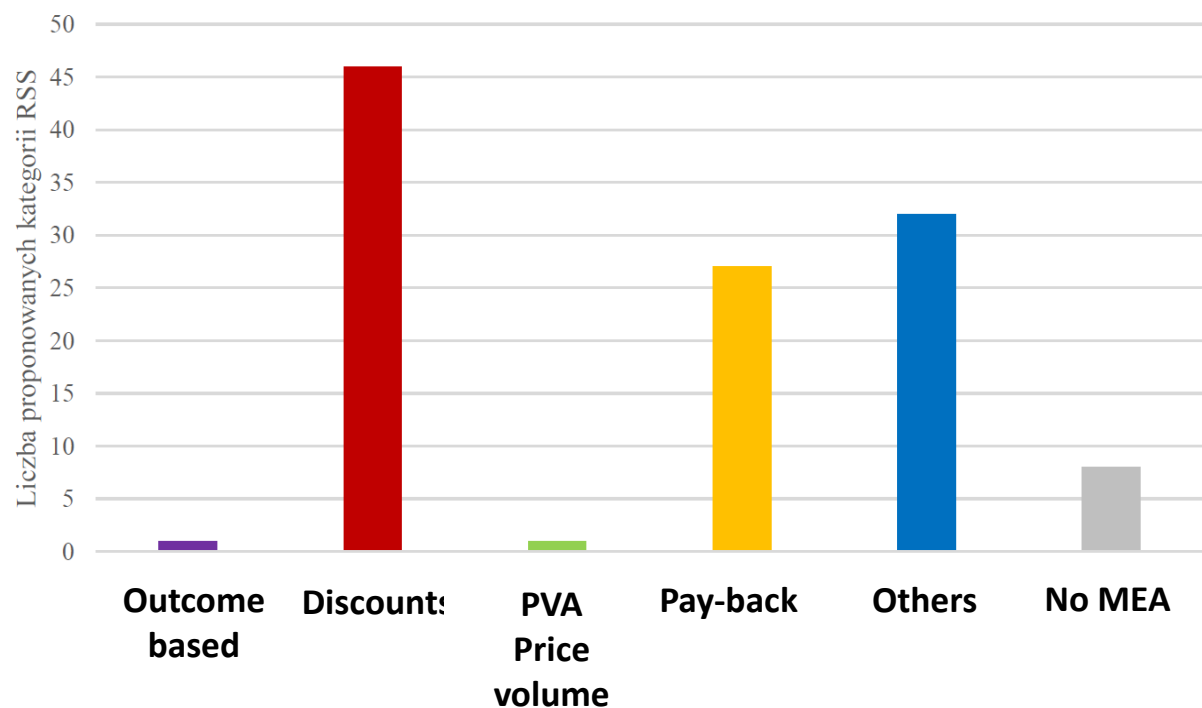
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MEAs - Managed Entry Agreements

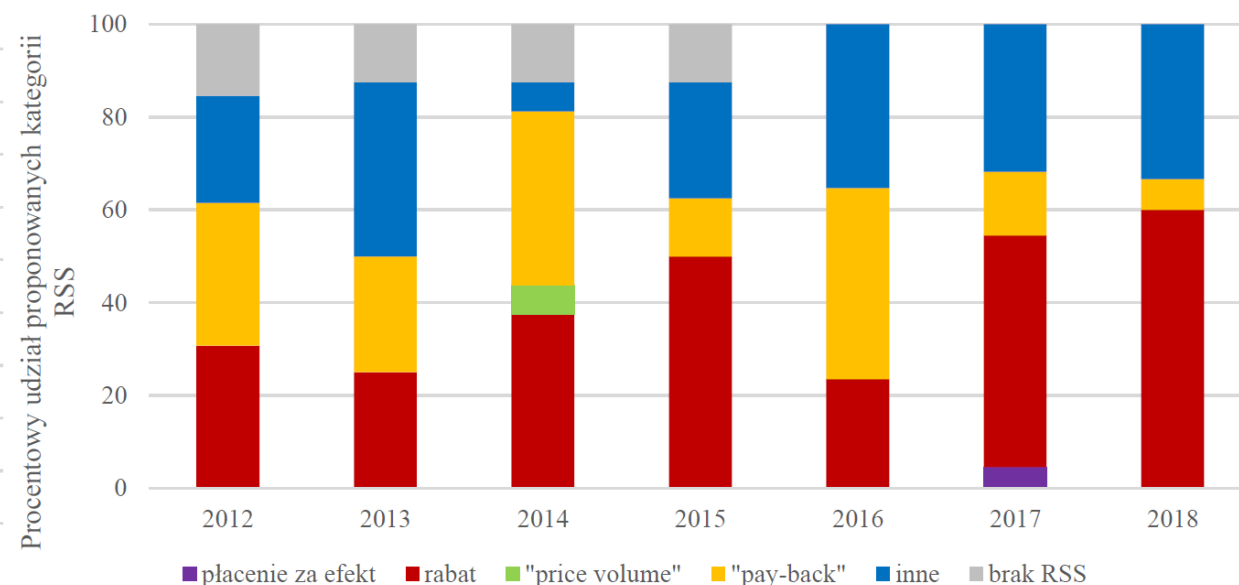
- Legal context:
 - Reimbursement act (2011) allows all kind of MEAs
 - Heavily explored and found not to be hurdle
- Majority of MEAs – purely financial: discounts, clawbacks, caps with listed price unchanged (RSS – „rebating secret system”)
- Reports on MEAs:
 - 2015, 2016 and 2018 – by Infarma and partners
 - 2019 – cancer drugs by HTA Agency (AOTMiT)

Cancer drugs – MEAs in reimbursement applications

MEAs types



MEAs 2012-2018



Analysis of risk sharing instruments proposed in reimbursement applications for drugs used in oncological diseases under drug programs, submitted to AOTMiT in 2012-2018. Iwańczuk et al. August 2019

Barriers in complex MEAs implementation

- Healthcare service contracting
- High administrative costs outweighing benefits
- High financial risk to payer related to quality of data reported
- Unfavorable negotiations not facilitating MEAs
- Public payer limited capacity
- Healthcare providers limited capacity
- Overloaded clinicians unmotivated to data reporting
- Limited use and effectiveness of electronic data systems available as integrated component of drug programs reporting

Final decision by MoH

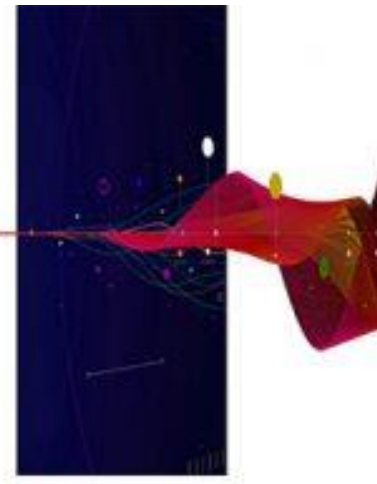
- Mainly financial MEAs – common
- Outcome-based MEAs – individual case(s)
 - N?
 - Price discount to adjust for non-responders (onco drugs)
- Confidential
 - Reimbursement regulation amendment –
 - MEAs details available for HTA Agency

Coverage with evidence development

- Medical Fund – 2020
- Highly innovative medicines
 - rare diseases and cancer
 - subject to outcomes based MEAs
 - effectiveness and safety analysis by HTA Agency based on the NHF data
 - 90 days before the end of the reimbursement period, the HTA Agency publishes a report on the evaluation of the effectiveness and quality of treatment based on data from medical registers (RWD)
- Medical Research Agency ?

MCDCA – multicriteria decision analysis

- Many qualitative MCDAs
 - (i.e. Iowisz - Evaluation Instrument of Investment Motions in Health Care)
- Announced by National Drug Policy 2018-2022
- Introduced in the Plan for rare diseases 2021
 - Quantitative MCDCA proposed as complimentary approach to standard C/E evaluation
 - Framework to be elaborated by HTA Agency
- Case studies, i.e.
 - Non-oncological diseases
 - Many papers and academic/independent projects



WIELOKRYTERIALNA ANALIZA DECYZYJNA
(MCDCA, MULTI-CRITERIA DECISION ANALYSIS)
W OCENIE TECHNOLOGII STOSOWANYCH
W NIEONKOLOGICZNYCH CHOROBYCH RZADKICH