

AGENCY FOR HEALTH TECHNOLOGY ASSESSMENT
AND TARIFF SYSTEM

Issue Panel: Managed Entry Agreements: Can CEE Countries Mutualize Lessons Learned?



Types of RSS Based on Statutory Provisions



In Poland, according to the reimbursement act, risk-sharing instruments may concern:

- ▶ Linking the applicant's **revenue** to achieved **health outcomes**;
- ▶ Linking the **net selling price** to the applicant's provision of **supplies at a reduced, negotiated price** for a drug, food for special medical purposes, or medical device;
- ▶ Linking the **net selling price** to the **sales volume** of a drug, food for special medical purposes, or medical device;
- ▶ Linking the **net selling price** to the **refund payback** to the entity responsible for public funding;
- ▶ Establishing **rules for the delivery and settlement** of drugs, foods for special medical purposes, and medical devices used in drug programs or chemotherapy;
- ▶ Setting **other reimbursement conditions** that impact **increased access to guaranteed benefits or reduced costs** of these benefits.

Confidentiality of Information Defined by Statutory Provisions



The applicant cannot claim the following information as confidential:

- ▶ Information on indications for which the drug, food for special medical purposes, or medical device is to be reimbursed;
- ▶ The content of the drug program project;
- ▶ The definition of the limit group as per the application;
- ▶ The fact of submitting a risk-sharing instrument proposal in the application;
- ▶ Information on reimbursement in other countries;
- ▶ Published information on clinical and practical effectiveness;
- ▶ Information on the safety of use (except for data from the Periodic Safety Update Report – PSUR);
- ▶ Information on the cost-effectiveness ratio without a risk-sharing instrument;
- ▶ Information on the cost-effectiveness of the assessed product;
- ▶ Information on the impact on public payer and patient expenditures without a risk-sharing instrument;

Confidentiality Challenges and Trade Secret Protection



1

Act on Combating Unfair Competition:

Protection of trade secrets—detailed RSS conditions as economically valuable information; such data cannot be freely exchanged without consent

2

EU Directive 2016/943

In principle, protection of trade secrets at the EU level if RSS details are covered by trade secrecy;

3

Reimbursement Act

In principle, exclusion of risk-sharing instruments from public disclosure (e.g., in verification analysis),

- scope of reimbursement secrecy.

4

Non-Disclosure Agreements (NDA):

May include a prohibition on disclosing the details of Risk-Sharing Schemes (RSS) during reimbursement negotiations.

Main Limitations in Implementing Joint Managed Entry Agreements



1

Differences in Reimbursement Systems and Thresholds

Countries evaluate values differently, which prevents straightforward harmonization of access criteria

2

Confidentiality of Price and Discount Conditions:

Limits the ability to compare and coordinate risk-sharing instruments across countries.

3

Asymmetry in Negotiating Power and Budget Capacity:

Smaller markets have weaker positions, leading to delayed or limited access to innovation.

4

Fragmented Standards for Clinical Evidence and Registry Data:

Differences in endpoint definitions and registry quality limit comparability and joint evaluations.

5

Absence of Permanent Cooperation and Joint Negotiation Structures

Reimbursement Process in the Context of RSS Evaluation



Applicant:

May choose to include, or not to include, a Risk-Sharing Scheme (RSS) proposal in the reimbursement application submitted to the Minister of Health.



Agency (AOTMiT):

Evaluates the feasibility of the RSS at the analytical stage and may propose modifications during the Transparency Council Opinion and Recommendation stages.



Economic Committee:

Negotiates price, scope of reimbursement, and RSS conditions.



Minister of Health:

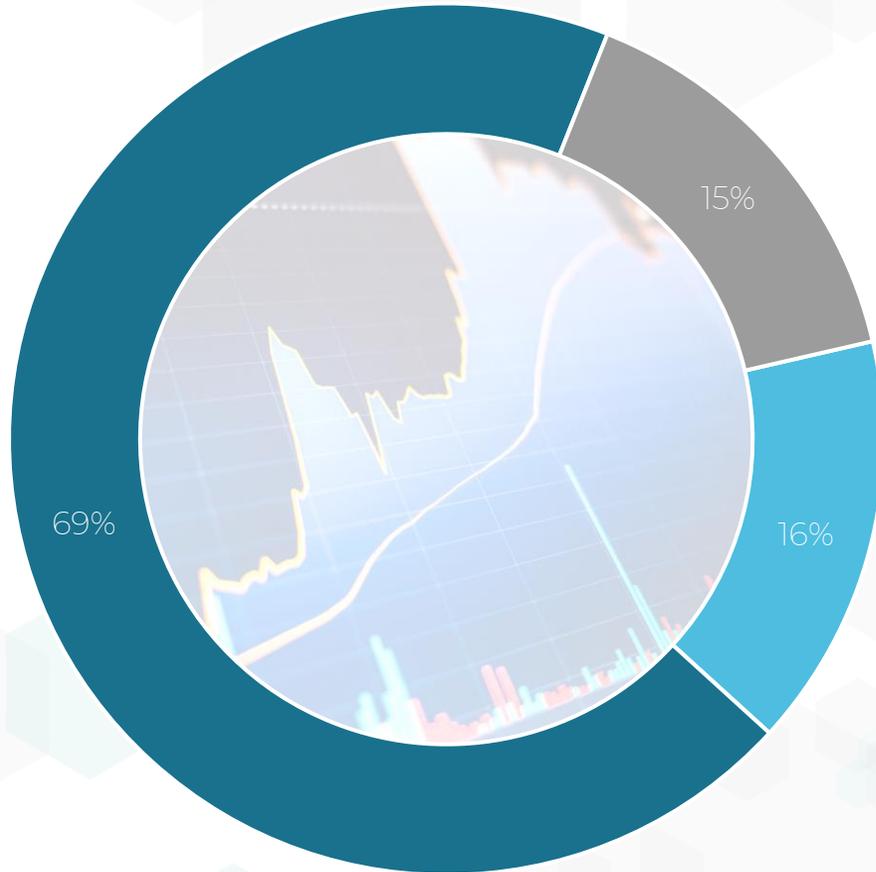
Takes the final reimbursement decision, specifying the scope of reimbursement and the terms of the Risk-Sharing Scheme

> The final RSS in the decision may be different than the applicant's proposal.

Risk-Sharing Schemes in Reimbursement Applications



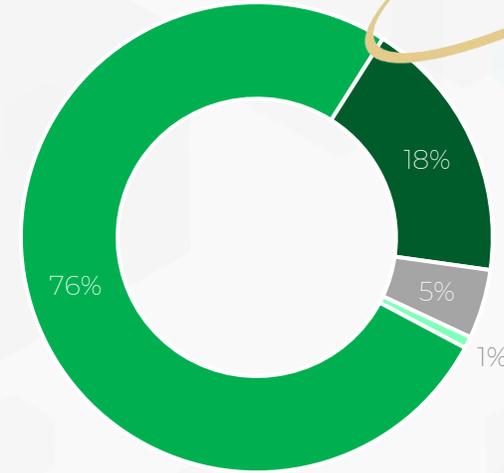
Applications with and without RSS



- Applications with and without RSS
- Single-component
- Multi-component

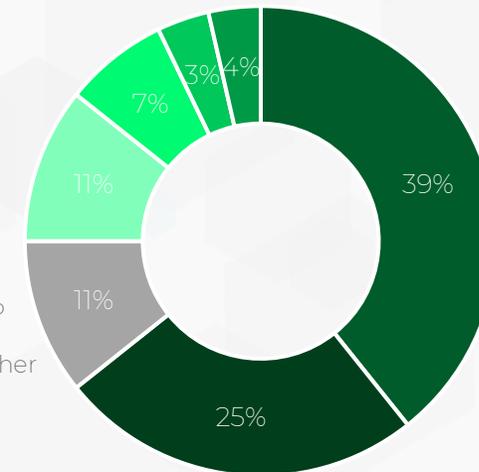
Single-component

- Discount
- Payback
- Other
- CAP



Multi-component

- Discount+Other
- Discount+Payback
- Discount+CAP
- Discount+Cap+Other
- Discount+Payback+CAP
- Discount+Payback+Other
- Payback+CAP



* Review of reimbursement applications assessed by the Agency in 2024 and 2025, for which Agency President's recommendations have been issued.

Innovative Drug Technology



AOTMiT prepares and submits the **List of Technologies with High Clinical Value** to the Minister of Health, in line with the Medical Fund Act and reimbursement legislation.

A medicinal technology for **oncology or rare diseases** that has received central marketing authorization within the **last year** and is included in the List prepared by the Agency.

Assessment Criteria of the List:

priorities, unmet need, evidence quality, clinical benefit and population size.

90 days prior to the end of the reimbursement period, AOTMiT issues an **effectiveness and quality-of-treatment report** using e-monitoring data, if sufficient clinical data are available.

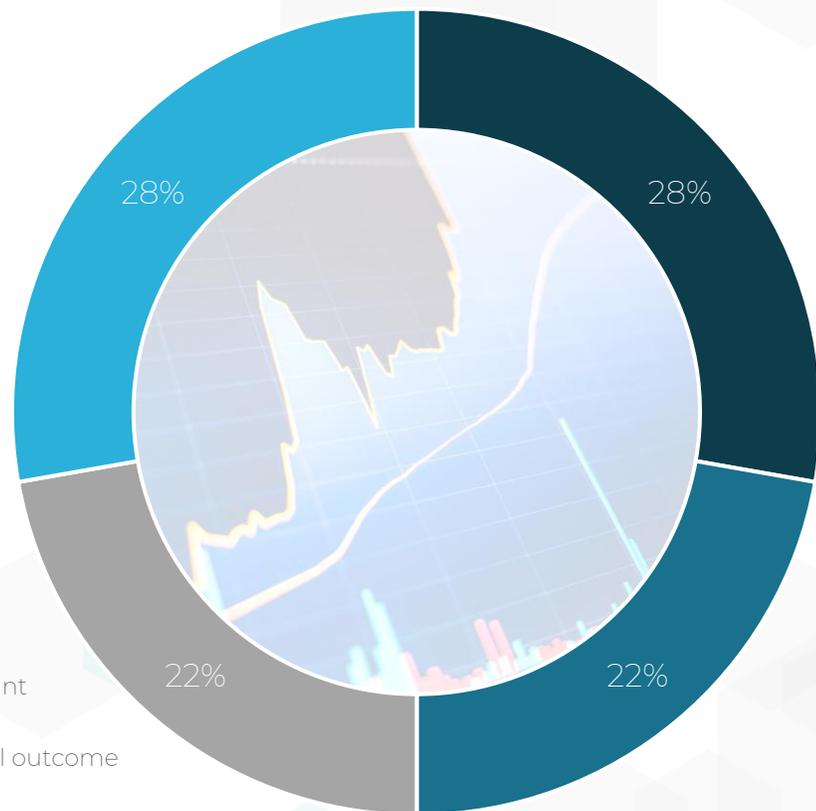
If **clinical data are insufficient**, the reimbursement is extended by 2 years, and AOTMiT publishes a report no later than 180 days before the expiry of the extended decision, based on available clinical data.



Use of RSS for Innovative Drug Technologies



All RSS were multi-component.



- Discount
- CAP
- Clinical outcome
- Other

RSS based on clinical outcomes was used in

80% of cases

Data for 2023–2025





THANK YOU
FOR YOUR
ATTENTION



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