# Risk Sharing Schemes

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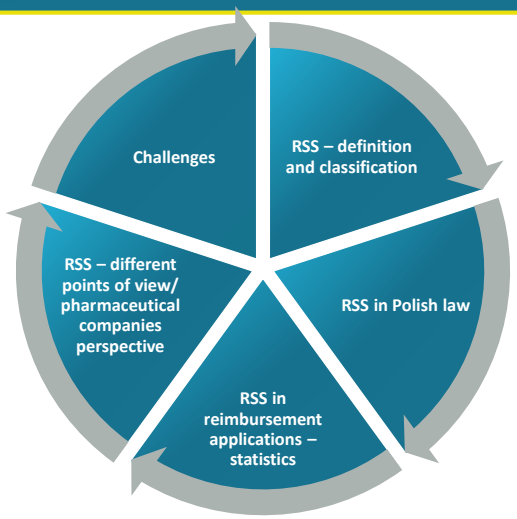
## Agenda



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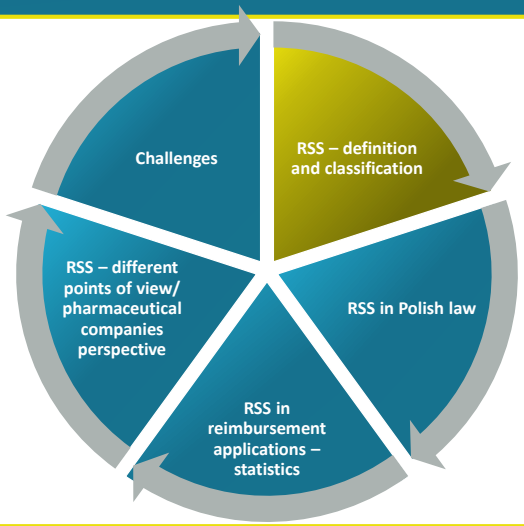
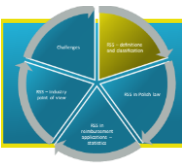


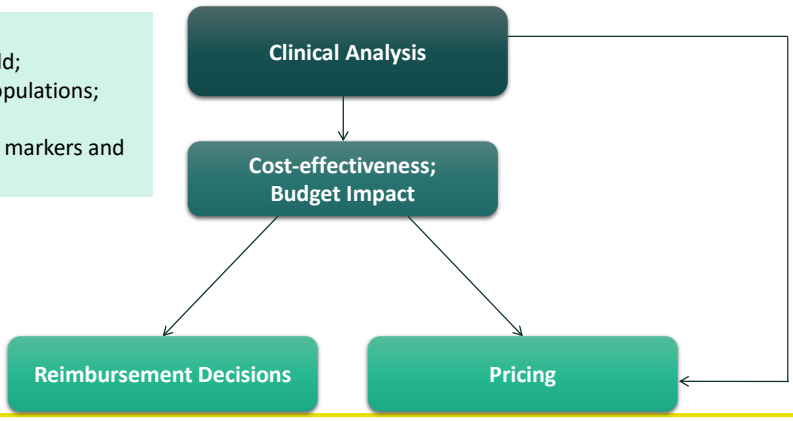


# The pervasiveness of uncertainty

***Medicinal products are approved, launched and reimbursed under conditions of uncertainty.***

- Efficacy (heterogeneity);
- Effectiveness in real world;
- Clinical benefits in subpopulations;
- Risks (safety);
- Links between surrogate markers and long-term outcome;



# Uncertainties & losses

**Risks**

**(financial, political, legal)**

**Market failure**

**Revenue loss**

Manufacturer

Regulator/Payer

**Making a bad decisions – incremental health benefits are not worth the additional cost**



# Purpose of RSS

**I** Enabling the **introduction** of new and costly medicines into the reimbursement system **in a better-controlled way**

**II** Increasing and **improving patients' access** to medicines and other products

**III** **Enhancing financial sustainability** of the reimbursement system

**IV** **Increasing flexibility** of shaping the **pricing** and **reimbursement** policy


# RSS – classification

## Financial utilization scheme:

- Price-Volume Agreement
- Payback
- Utilization Caps (CAP)

## Risk based pricing scheme:

- Conditional coverage and evidence development
- Outcome based pricing scheme
- Payment by results

Carlson JJ, Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL.Linking payment and health outcomes: a systematic review and taxonomy of performance-based health outcomes agreements between health care payers and manufacturers. Blackwell Publishing Inc.; 2009. http://www.valueinhealthjournal.com/article/S1098-3015(10)73513-0/abstract. Accessed 13 April 2015.


# Risk Sharing Agreements

## Financial-based

**Based on total costs of drug to treat the <u>population</u>:**

- Capping of drug expenses, after which a discount or payback is applied;
- **Price/volume agreement** with unitary price reduction after a certain volume is reached;

**Based on total costs of drug to treat the <u>patient</u>:**

Capping of the treatment. Examples:

- Maximum number of reimbursed doses, after which the MAH commits to supply the remaining doses;
- The reimbursed treatment duration is agreed, after which the MAH support the additional costs required to complete the treatment;
- Maximmum limit for the costs of treatment per patient after which it is supported by the MAH;

## Outcome-based

**Outcomes guarantees:**

Payer only supports costs of patients responding to treatment; costs of treatment of patients not reaching a predetermined response are fully or partially paid by the MAH;

**Coverage with evidence development:**

Allows access to the drug while evidence is generated; reimbursement continuation, including price and reimbursement conditions, may be dependent on additional data gathering and presentation;

**Conditional treatment continuation:**

Only patients achieving a previously defined level of response are eligible for reimbursement.

Gonçalves FR, Santos S, Silva C, Sousa G. Risk-sharing agreements, present and future. *Ecancermedicalscience* . 2018; 12: 823.

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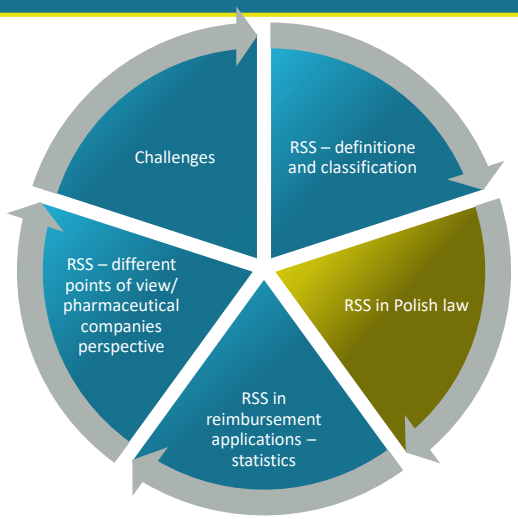




# RSSs in the Polish Act on Reimbursement (1/2)

**Risk Sharing Scheme was introduced by the Act of 12 May 2011 on Reimbursement of Medicinal Products, Food for Special Nutritional Purposes and Medical Devices**

1. *making the level of the applicant's* ***revenues dependent on the health effects achieved*** → Discount
2. *making the official* ***sales price dependent on the applicant providing supplies at the reduced price****, as specified in the negotiations on the price of the medicine* → Price-volume
3. *making the official* ***sales price dependent on the level of turnover*** *of the medicine* → Price-volume

Article 11 (5) of the Act on Reimbursement

# RSSs in the Polish Act on Reimbursement (2/2)

4. *making the official sales price dependent on a **pay-back of a part of the reimbursement obtained to the entity**, which is obliged to finance benefits through public funds;*

Pay-back

5. ***other reimbursement conditions** that have an impact on increasing the availability of guaranteed services or reducing the cost of these benefits.*

Others – combination of 2 or more categories or not fitted into any of the categories (eg sales without going through wholesalers or providing medical devices)

Article 11 (5) of the Act on Reimbursement



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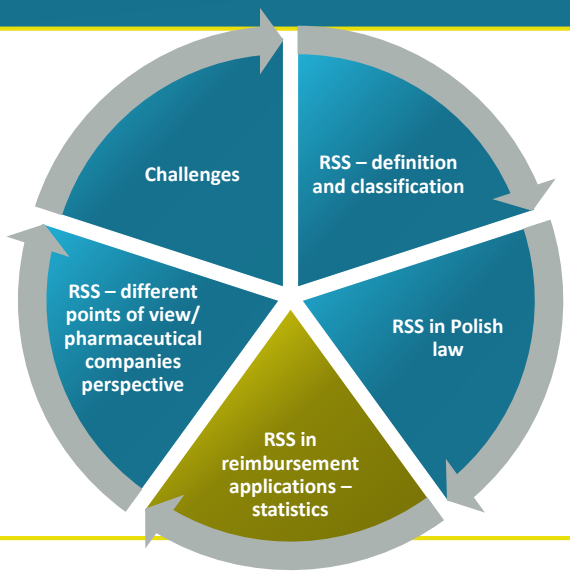
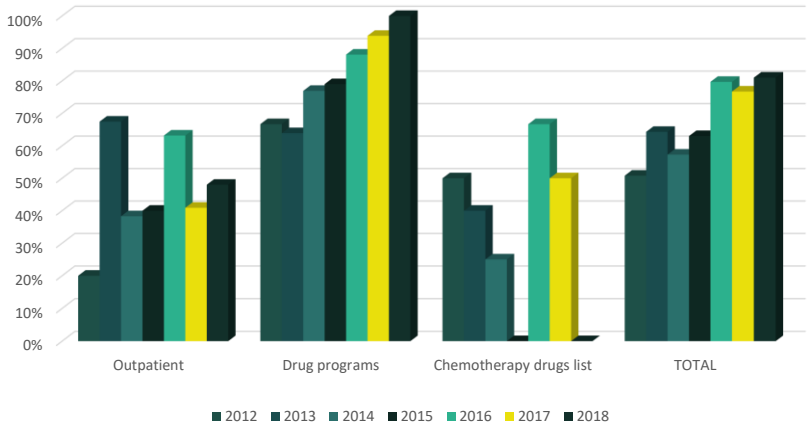
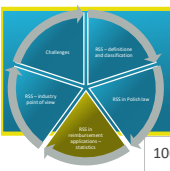



# Percentage of the applications with RSS classified by the reimbursement category

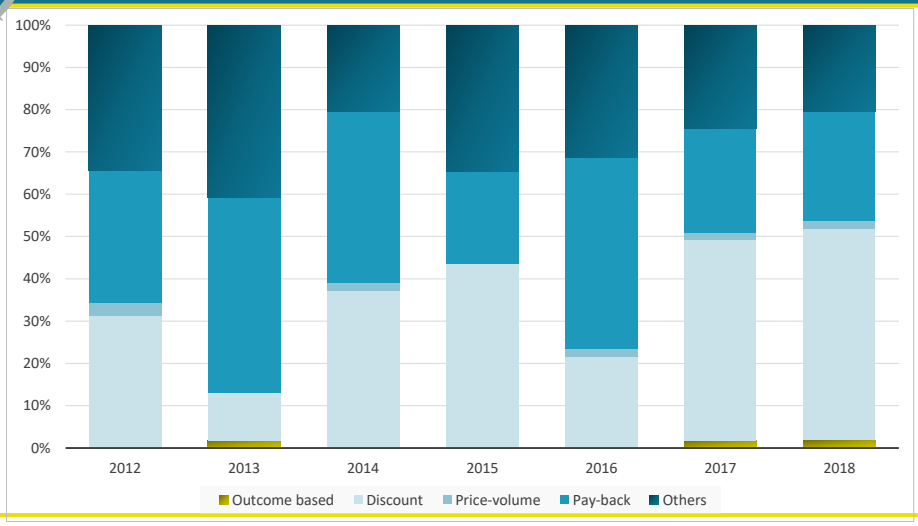
**RSS from application** (not from reimbursement system)






# Types od RSSs in reimbursement applications




*Although most agreements are still financial in nature, there is already a strong desire for other agreements, in particular clinical outcomes based.*

# Conclusions from reimbursement applications

Chemotherapy drugs list*– in 2012-2018 there was only 20 applications, 8 included RSS proposal

**Most often proposed arrangements were: simple discounts or pay-back**

– ease of implementation and management

80% of all applications had RSS proposal

**In 2018 100% applications for financing within drug programs** (the most expensive drugs) had a RSS proposal (mostly discount)

**50% of applications for financing within outpatient care** had RSS proposal (mostly pay-back)

*list of a reimbursed medicinal products used in chemotherapy but not financed under drug programs



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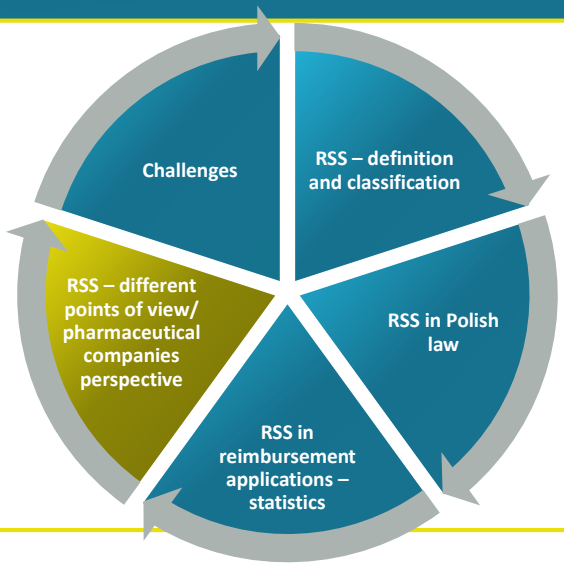

# Advantages and disadvantages of RSA - different perspectives

| Perspective | Advantages | Disadvantages |
|---|---|---|
| Patients/society | ▪ Access to innovative medicines;<br>▪ More treatment options and potential health improvement;<br>▪ Promotion of investment for innovation; | ▪ Risk of the medicine not displaying the expected benefit;<br>▪ **Discontinuation of access to medicine at the end of the agreement**;<br>▪ Issues relating to **data protection**; |
| Providers | ▪ Greater knowledge and improved disease management;<br>▪ Access to innovative medicines;<br>▪ Limiting budget impact;<br>▪ Reduction of uncertainty concerning effectiveness; | ▪ **Costs/bureaucracy** of implementation and monitoring of the agreement;<br>▪ **Computerization of data and follow-up** of patients complex/costly;<br>▪ Complexity of multiple agreement management; |
| Payers | ▪ Collection of additional evidence (that supports financing decision);<br>▪ Management of uncertainty (effectiveness and budget);<br>▪ Therapy directed at patients with potential to benefit (avoiding risk in patients who would not benefit); | ▪ Difficulty in **defining easily measurable performance indicators**;<br>▪ **Lack of integrated information system** that allows data collection at local and national level;<br>▪ Intensive allocation of **resources in data collection** and analysis/monitoring of the agreement; |
| Pharmaceutical companies | ▪ Access of innovative medicines to the market;<br>▪ Improved performance of medicine due to use for target patient;<br>▪ Innovation rewarded and R&D stimulated;<br>▪ Terms of agreement confidential, including price; | ▪ **Costs/bureaucracy** of implementation and monitoring of the agreement;<br>▪ **Risk of not demonstrating alleged effectiveness**;<br>▪ **Financial unpredictability**, depending on the type of agreement;<br>▪ **Biased selection of patients with worse prognosis**; |

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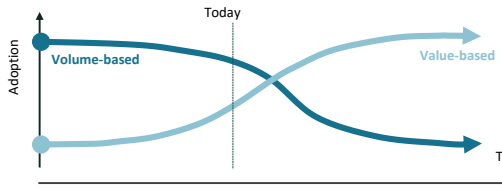
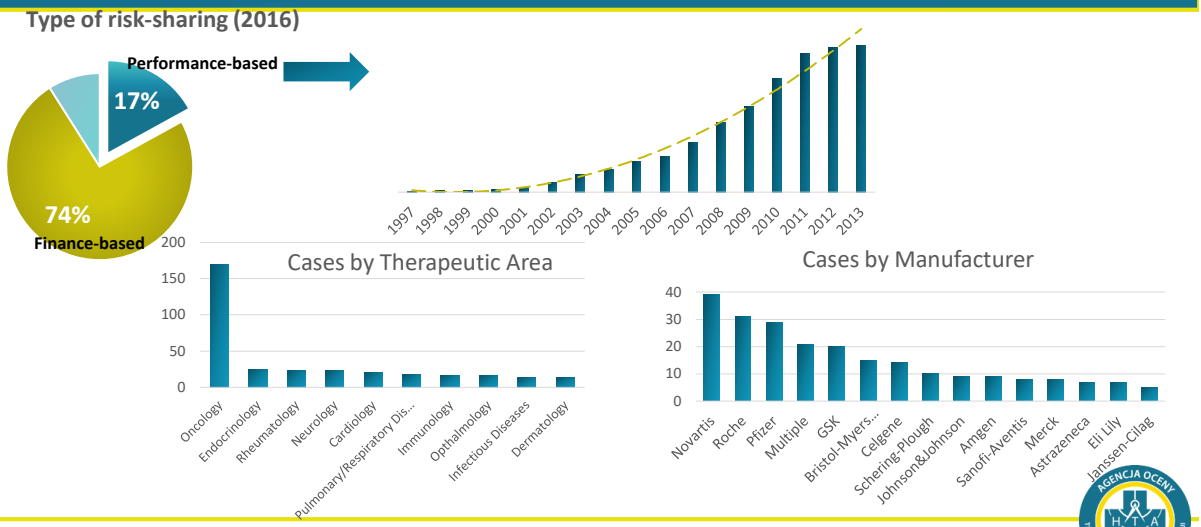
# Push for Value-Based Pricing




*Performance-Based Risk Sharing Arrangements;*
*Diversification of RSAs to Fit the Purpose*

| | From Volume-Based | … To Value-Based |
|---|---|---|
| Patients | ➢ Limited access to health data | ➢ Improved patient tracking and monitoring technology |
| Manufacturers | ➢ Rx based revenue model | ➢ Real life data collection<br>➢ Increased investment in data management (registries)<br>➢ Implementation new and improved systems to keep pace with modern healthcare needs |

# Performance-based schemes




UW PBRSA Database 2016



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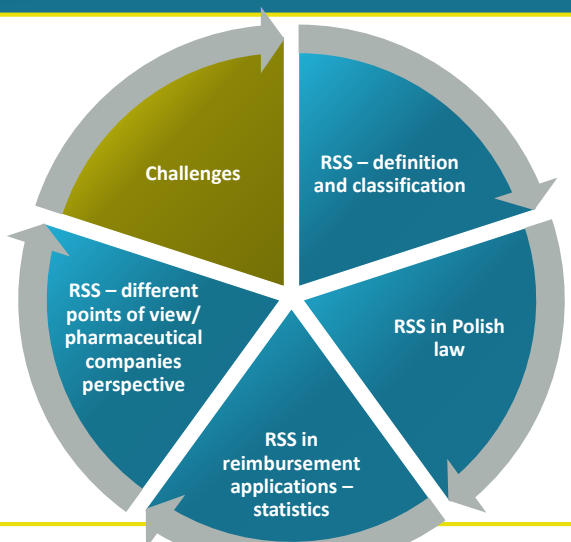



# Challenges

**Registries and „real world data”**

**Cooperation between MoH, Payer, Agency in building most efficient RSS**

**Building more „tailored” RSS for each therapy**

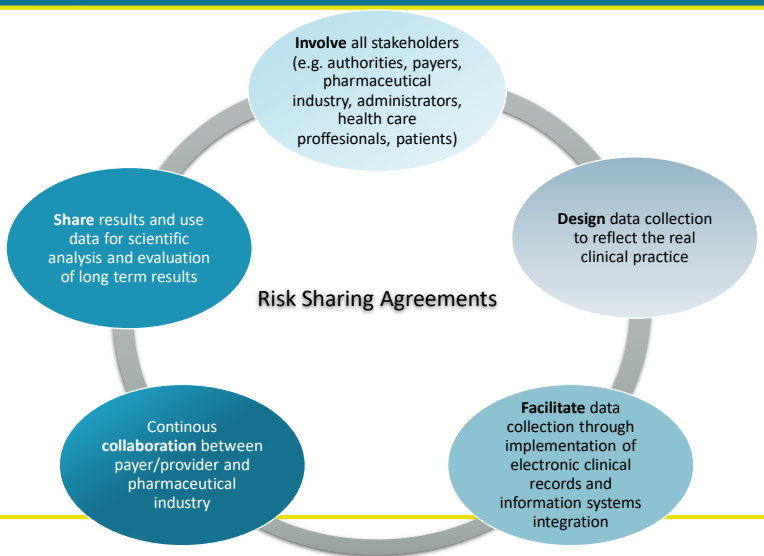
**Improving quality of data reporting to the Payer**

**Creating more „tools” which will help to negotiate – get lower price and access to new technologies**

**Is outcome based RSS the best solution?**



# Recommendations for RSSs



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