ISPOR Europe 2019 2-6 November 2019 Copenhagen, Denmark

RESEARCH INSTITUTE FOR HEALTHCARE ORGANIZATION AND MEDICAL MANAGEMENT

PROBLEMS OF IMPLEMENTATION OF RISK SHARING SCHEMES IN THE COUNTRIES OF CENTRAL AND EASTERN EUROPE AND THE WAYS OF THEIR SOLUTION

Tatiana Kurnosova
Malwina Holownia-Voloskova

RISK-SHARING AGREEMENTS
Russian experience

1 Guidelines and other works on the subject

2 Opinions of different government structures

3 Projects of RSAs

4 Development of RSAs

12

RISK-SHARING AGREEMENTS development in Russia

- 1.1. **Development** and submission of the application by the manufacturer
- 1.2. **Evaluation** of the application and draft recommendation by the center
- 1.3. **Transfer** of the recommendation of the center to the payer
- 1.4. Trilateral **negotiations** payer - center – manufacturer
- 1.5. **Improvement and approval** of the developed RSA with its implementation and monitoring plan. Definition of **confidentiality** of documents
- 1.6. **Choice** of the hospital by the payer
- 1.7. **Meeting** payer - center - manufacturer - distributor - wholesaler - hospital (pharmacy). Appointment of persons responsible for implementing the scheme.

13

Кокушкин К., Давыдовская М., Холовня-Волоскова М. и соавт. Методические рекомендации по разработке, внедрению, мониторингу и оценке соглашений о разделении рисков – составной части инновационных моделей лекарственного обеспечения. Правительство Москвы, ДЗМ, Издательство РООИ «Здоровье человека», Москва 2018

RISK-SHARING AGREEMENTS implementation in Russia

- 2.1. Development of **legislative acts** for implementation
- 2.2. **Provision** of conditions of implementation (software, training of medical and other personnel involved in performance of the scheme)
- 2.3. **Starting** a scheme
- 2.4. **Evaluation** of the efficiency of implementation by the center in cooperation with hospitals (pharmacies)

14

Кокушкин К., Давыдовская М., Холовня-Волоскова М. и соавт. Методические рекомендации по разработке, внедрению, мониторингу и оценке соглашений о разделении рисков – составной части инновационных моделей лекарственного обеспечения. Правительство Москвы, ДЗМ, Издательство РООИ «Здоровье человека», Москва 2018

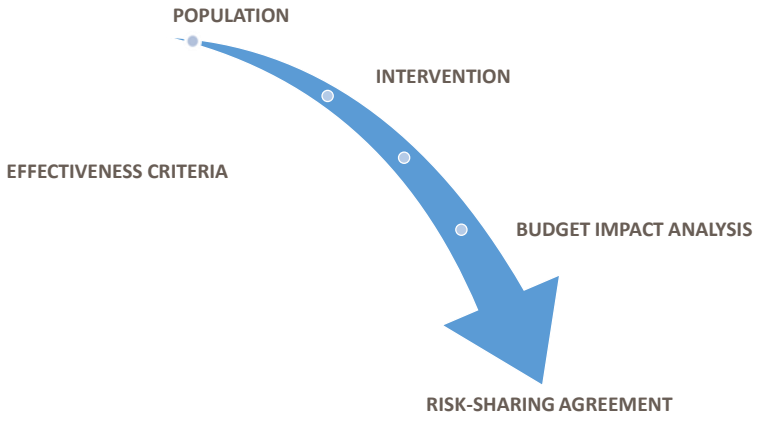
RISK-SHARING AGREEMENTS
monitoring in Russia

- 3.1. **Data collection**
- 3.2. **Data processing** and analysis by the center
- 3.3. **Reporting** by the center
- 3.4. **Assessment** of the effectiveness of the scheme by the payer. **Findings**.

15

Кокушкин К., Давыдовская М., Холовня-Волоскова М. и соавт. Методические рекомендации по разработке, внедрению, мониторингу и оценке соглашений о разделении рисков – составной части инновационных моделей лекарственного обеспечения. Правительство Москвы, ДЗМ, Издательство РООИ «Здоровье человека», Москва 2018

RISK-SHARING AGREEMENTS
Russian experience – road to RSA

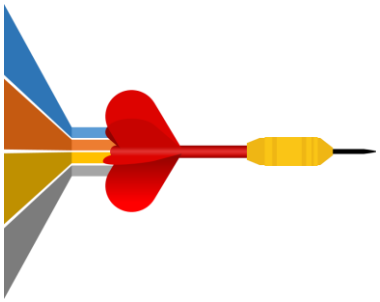


16

Кокушкин К., Давыдовская М., Холовня-Волоскова М. и соавт. Методические рекомендации по разработке, внедрению, мониторингу и оценке соглашений о разделении рисков – составной части инновационных моделей лекарственного обеспечения. Правительство Москвы, ДЗМ, Издательство РООИ «Здоровье человека», Москва 2018

RISK-SHARING AGREEMENTS
elements of RSAs in Russia

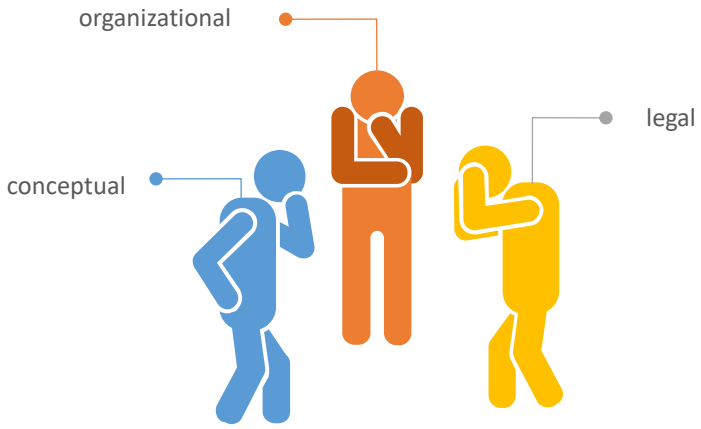
1. Detailed **specification of the parties** to the agreement.
2. Determining the **type** of agreement.
3. **Definition of medical technology** that is considered as the subject of the RSA.
4. The **reason** the payer has decided that he will finance the treatment with RSA.
5. Determining the treatment **regimen** and the **amount** of the drug for which the payer pays.
6. Description of **therapy monitoring system**.
7. Definition of what is considered a "**response to treatment**" for a particular RSA.
8. Determination of the **lack of effect** in the RSA and related sanctions.
9. Determination of **conditions that exclude the return of treatment costs**, even in the case of a negative clinical effect.
10. Determination of the **duration** of the contract and the period of time after which the contract will be evaluated and calculated.
11. Description of the **method of returning expenses** (or packages) to the payer.
12. Determining the **source of data on the course of therapy** - who, where and when.



17

Кокушкин К., Давыдовская М., Холовня-Волоскова М. и соавт. Методические рекомендации по разработке, внедрению, мониторингу и оценке соглашений о разделении рисков – составной части инновационных моделей лекарственного обеспечения. Правительство Москвы, ДЗМ, Издательство РООИ «Здоровье человека», Москва 2018

RISK-SHARING AGREEMENTS
limitations in Russia



18

RISK-SHARING AGREEMENTS
conceptual limitations (1)

According to Russian FAS, RSAs are possible only for monopoly drugs when:

1) the drug is protected by **patent**;

2) there are **no interchangeable** medicinal products or analogues registered;

3) the drug is **innovative**;

4) the drug is **not included in VEDL**, due to its high cost and the lack of budget funds for its purchase, low evidence base for its efficacy, lack of information from post-registration safety CT (implementation of VEDL drugs may lead to the risk of suppliers refusing to participate in tenders, which can violate the rights of citizens to medical care due to the lack of those drugs);

5) the **max. selling price of the drug is agreed between all RSA parties** at a level not exceeding the price calculated in accordance with the methodology for calculating the max. selling prices for VEDL drugs;

19

RISK-SHARING AGREEMENTS
conceptual limitations (2)

6) the need to use a drug is due to the **impossibility of using other drugs** and is aimed at ensuring citizens' rights **to access innovative drugs** in life-threatening conditions or as palliative therapy;

7) RSAs should be carried out **to assess the economic efficiency** of drugs use, so the supplier of the drug should be 100% compensated for the budget costs in the event of a negative pilot project;

8) patients who are recipients of a drug provided by RSA **must be insured** in accordance with Article 44 of the 61-FZ “On the Circulation of Medicines”;

9) the pilot project is carried out according to **uniform rules**, requirements, sample documents developed and approved by Russian MoH.

20

RISK-SHARING AGREEMENTS
legal limitations (1)

- The procurement of medicines necessary to ensure state functions to provide guarantees of free medical care is regulated by legislation:

1) on the state contract system,
2) antimonopoly legislation,
3) legislation on medicines,
4) number of by-laws and departmental regulatory legal acts.

- In particular, in accordance with the Order of the Government of the Russian Federation dated March 21, 2016 N 471-r, **medicines are classified as goods, the purchase of which for state or municipal needs should be carried out through an auction in electronic form**.

21

RISK-SHARING AGREEMENTS
legal limitations (2)

RSAs should provide:

- **register** of patients who meet the criteria for participation

- development, coordination with manufacturer and approvement legal acts:

1) procedure and terms for **monitoring** the effectiveness of drug therapy;
2) procedure and timing for the **transfer** of materials for consideration by WG on RSA;
3) conditions for the **implementation** of RSA;
4) procedure for **evaluating** the effectiveness of drug therapy;
5) procedure and conditions for confirming the **absence of signs** of clinical progression of the disease in a particular patient;
6) procedure for confirming the **need to continue** drug therapy for a particular patient.

Regional government bodies should issue 7 legal acts regulating the relationship between the customer and the supplier of medicines in the RSA framework.

22

RISK-SHARING AGREEMENTS
legal limitations (5)

- development of these procedures and their approval by regional legal acts **is not included** in the powers of state authorities of the constituent entities of the RF;
- RSA may lead to the formation of **different requirements** in the subjects, participating in the same RSA, which may cause discrimination of other drug suppliers;
- art.16 of 135-FZ "On the Protection of Competition" **prohibits agreements** restricting competition by state authorities and business entities - mechanism for preliminary approval of the conditions may be anti-competitive;
- mechanism of the RSA implementation should contain provisions disclosing the **consequences of terminating** the agreement between the MoH and the subject;
- the RSAs could be enslaving for government, since they make the possibility of implementing a RSA directly **dependent on the actions** (including intentional) of 3rd parties (members of the WG, medical workers, etc.).

23

RISK-SHARING AGREEMENTS
organizational limitations

- PAYER:
  - Which entity should be competent to conclude such an agreement?
  - Who should train the staff responsible for RSA?
  - What should be their level of confidentiality?
- WORKING GROUP:
  - Who should train the staff responsible for RSA?
  - Should an ad hoc group be assigned to be responsible for negotiating agreements?
  - How should negotiations on the price be held?
  - What should be their level of confidentiality?

24

RISK-SHARING AGREEMENTS
organizational limitations

- MONITORING:
  - Who should monitor the implementation of agreements?
  - Who should train them?

- SOFTWARE & PATIENT REGISTRIES:
  - Who should develop the software?
  - Who should pay for the appropriate patient registers?

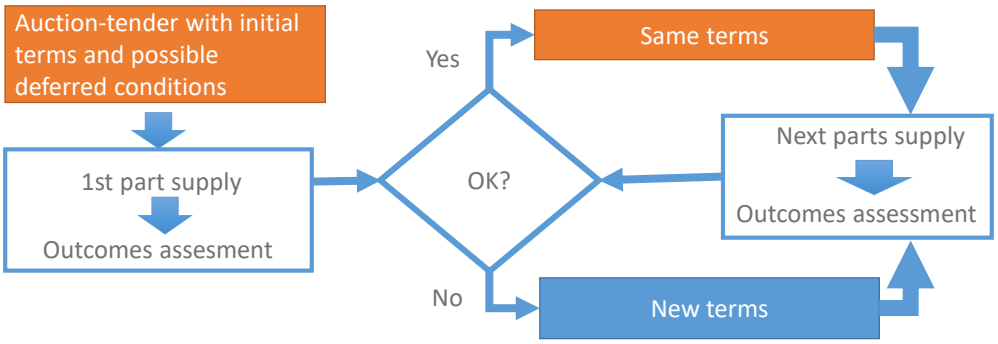
- DATA:
  - Who is the owner of the data, collected during RSA?
  - Can it be published?

25

RISK-SHARING AGREEMENTS
conceptual problems - solutions

I. Within one contract with drug supplier

Health outcomes (HO) are considered as **unexpected deferred conditions** (unknown will it happened or not, civil code, article 157). It can include compensation or proportional decrease of contract total price. All specific outcomes and contract terms have to be clearly stated in initial contract.



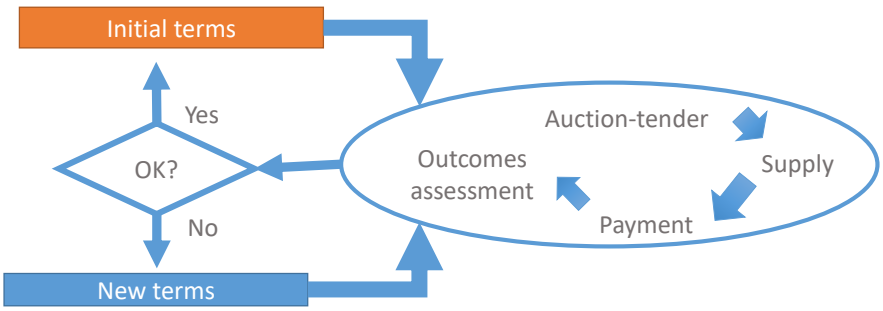
26

Tolkushin A, Kokushkin K, Davydovskaya M, Ermolaeva T. Allowability of outcomes-based risk-sharing schemes in Russia within current legislative hurdles. Poster on ISPOR 21th Annual European Congress

RISK-SHARING AGREEMENTS
conceptual problems - solutions

II. Within several consecutive purchases

Health outcomes are considered as a basis for **review of starting terms** for the next auction. This option implies preliminary local act with detailed description of the scheme. This option is most risky for the industry.



27

Tolkushin A, Kokushkin K, Davydovskaya M, Ermolaeva T. Allowability of outcomes-based risk-sharing schemes in Russia within current legislative hurdles. Poster on ISPOR 21th Annual European Congress

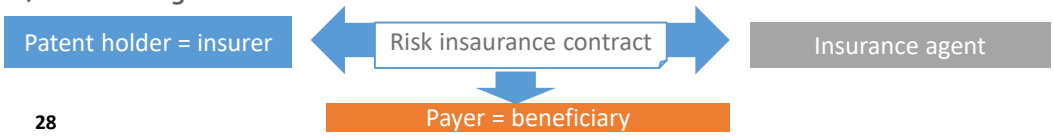
RISK-SHARING AGREEMENTS
conceptual problems - solutions

III. Within separate agreements

Outcomes compensation agreement (or outcomes risk insurance agreement) with third party (e.g. industry) can be separated from supply contract with drug supplier auction winner.

a) Compensation agreement

b) Insurance agreement



28

Tolkushin A, Kokushkin K, Davydovskaya M, Ermolaeva T. Allowability of outcomes-based risk-sharing schemes in Russia within current legislative hurdles. Poster on ISPOR 21th Annual European Congress

RISK-SHARING AGREEMENTS
legal problems – solutions

The basic model of drug supply for the procurement of drugs

Actions					
	Planning	Tender	Supply	Payment	Treatment
Doc-s					
	Schedule, tender doc-s, draft state contract	Gov. contract	Delivery doc-s		

29

Holownia-Voloskova M, Tolkushin A, Davydovskaya M, Kurnosova T, Ermolaeva T, Kokushkin K. regulatory basis for the organization of risk-sharing schemes in the Russian Federation. Poster on ISPOR 2019, New Orleans, US.

RISK-SHARING AGREEMENTS
legal problems – solutions

Option "1„ with suspensive conditions

Actions						
	Planning	Tender	Supply	Payment	Treatment	Evaluation of treatment
Doc-s						
	Schedule, tender doc-s, draft state contract	Gov. contract	Delivery doc-s	Performance evaluation protocol	App. to gov. contract with new conditions	Gov. contract with suspensive conditions

30

Holownia-Voloskova M, Tolkushin A, Davydovskaya M, Kurnosova T, Ermolaeva T, Kokushkin K. regulatory basis for the organization of risk-sharing schemes in the Russian Federation. Poster on ISPOR 2019, New Orleans, US.

RISK-SHARING AGREEMENTS
legal problems – solutions

Option "2" with the subsequent purchases

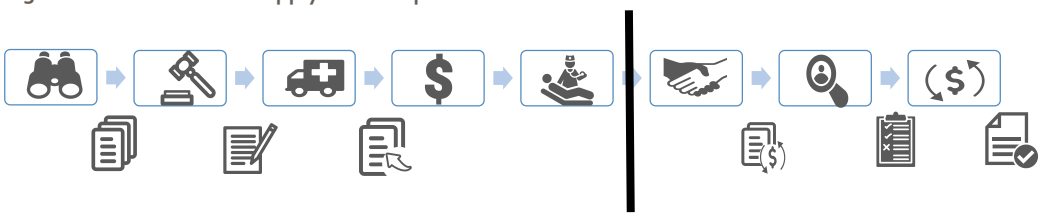
Actions	Planning	Tender	Supply	Payment	Treatment	Evaluation of treatment	Revision of the initial max contract price
Doc-s	Schedule, tender doc-s, draft state contract	Department document	Delivery doc-s	Gov. Contract	Performance evaluation protocol		

31

Holownia-Voloskova M, Tolkushin A, Davydovskaya M, Kurnosova T, Ermolaeva T, Kokushkin K. regulatory basis for the organization of risk-sharing schemes in the Russian Federation. Poster on ISPOR 2019, New Orleans, US.

RISK-SHARING AGREEMENTS
legal problems – solutions

Option "3" with the division of supply and compensation



Actions	Planning	Tender	Supply	Payment	Treatment	Evaluation of treatment	Compensation agreement	Compensation
Doc-s	Schedule, tender doc-s, draft state contract	Gov. contract	Delivery doc-s	Performance evaluation protocol	Compensation document	Act of mutual settlements		

32

Holownia-Voloskova M, Tolkushin A, Davydovskaya M, Kurnosova T, Ermolaeva T, Kokushkin K. regulatory basis for the organization of risk-sharing schemes in the Russian Federation. Poster on ISPOR 2019, New Orleans, US.

RISK-SHARING AGREEMENTS
organizational limitations – search for solutions

- PAYER:
  - Which entity should be competent to conclude such an agreement?

Federal or regional?

  - Who should train the staff responsible for RSA?

Entity that is responsible for RSA in or out of cooperation with patent holder?

  - What should be their level of confidentiality?

Depending on the involvement to the process or the same for everyone?

- WORKING GROUP:
  - Who should train the staff responsible for RSA?

Entity that is responsible for RSA in or out of cooperation with patent holder?

  - Should an ad hoc group be assigned to be responsible for negotiating agreements?

Or should it be the working group?

  - How should negotiations on the price be held?

Transparent, half-confidential or confidential?

  - What should be their level of confidentiality?

Depending on the involvement to the process or the same for everyone?

33

RISK-SHARING AGREEMENTS
organizational limitations – search for solutions

- MONITORING:
  - Who should monitor the implementation of agreements?

Working group members or someone else?

  - Who should train them?

Entity that is responsible for RSA in or out of cooperation with patent holder?

- SOFTWARE & PATIENT REGISTRIES:
  - Who should develop the software?

Independent organization, patent holder or payers' representative?

  - Who should pay for the appropriate patient registers?

Patent holder or payer?

- DATA:
  - Who is the owner of the data, collected during RSA?

Patent holder or payer?

  - Can it be published?

With what kind of transparency?

34

Thank you!

Q&A: malwina.holownia@gmail.com