

# HOW CAN RISK-SHARING AGREEMENTS IN KOREA BE IMPROVED?

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*h-well*  
National Health  
Insurance Service



## Payer's Perspectives

*h-well*  
National Health  
Insurance Service



## Background

### *Government*

- Enforcement of benefit coverage extension for 4 main severe diseases since 2013

### *Industry*

- Demand for reflecting a proper value of new drug on price
- Desire to maintain global price



Begin to discuss on Risk Sharing Agreement(RSA) to increase patients' access to new drug

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## Stakeholders' Opinion

### PROS

#### *Patients' Group*

- To strengthen patients' access to new drug

#### *Pharmaceutical Industry*

- To strengthen patients access to new drug
- To minimize effects of External Reference Pricing

### CONS

#### *Civic Group and Insurant Group*

- Misused as an easy entry method by MNC
- Against the principle of PLS
- Lowering transparency of drug pricing policy
- Threatening health right
- Increasing drug price and patients' co-payment

*MNC: Multinational pharmaceutical corporation  
PLS: Positive Listing System*

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## Risk Sharing Agreement in KOREA

- **Available for limited drug**
  - Anti-cancer or rare disease treatment with no alternative
- **Within Positive Listing System**
  - Need to prove cost-effectiveness of new drug
- **Major difference from ordinary drugs**
  - F2F deliberation in Health Insurance Policy Deliberative Committee
  - Re-evaluation before expiring of contract
  - Restriction of reimbursement criteria expansion during contract period
- **No increase of patients' co-payment**
  - If additional patient's co-payment occurred, refund the difference to patient

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## Drug List of Risk Sharing Agreement

**Total 11 drugs (8 Refund, 2 Expenditure Cap, 1 CED)**

No.	Product	Active Compound	Company	RSA Type
1	Evoltra	Clofarabine	Genzyme	CED
2	Revlimid	Lenalidomide	Celgene	Refund
3	Erbix	Cetuximab	Merck	Refund
4	Xtandi	Enzalutamide	Astellas	Refund
5	Xalkori	Crizotinib	Pfizer	Refund
6	Pirespa	Pirfenidone	Ildong	Refund
7	Soliris	Eculizumab	Handok	Refund
8	Caprelsa	Vandetanib	Genzyme	Expenditure Cap
9	Naglazyme	Galsulfase	Samoh	Refund
10	Vimizim	Elosulfase	Samoh	Expenditure Cap
11	Stivaga	Regorafenib	Bayer	Refund

CED: Coverage with Evidence Development

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## Amendment (1/2)

### Procedure for termination of a contract before expiration('15.Dec.)

- **If the company wants to terminate the contract before expiration, it can be terminated through the same process as when the contract expires**
  - DREC evaluation + negotiation with NHIS
- **Early termination would not be allowed in case of**
  - Specific RSA type(i.e. CED, Expenditure cap)
  - Failure of negotiation about the price that is supposed to be applied after the termination

*DREC: Drug Reimbursement Evaluation Committee  
CED: Coverage with Evidence Development*

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## Amendment (2/2)

### Procedure for reimbursement criteria expansion during the contract period('16.Jul.)

- **The expansion range should be subject to risk-sharing agreement, if not, cost-effectiveness in expansion range has to be proved**
- **The contents of contract has to be changed through the negotiation between NHIS and company, after the evaluation of DREC**
- **In negotiation process, additional budget impact, administration cost of substitutes and foreign countries' price will be considered**

*\* Internal guideline of NHIS and HIRA will be amended in Sep. 2016*

*DREC: Drug Reimbursement Evaluation Committee  
HIRA: Health Insurance Review and Assessment Service*

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## Future Plan

- **'Consultative Body for Improving drug price policy' will examine and discuss overall operation methods of RSA(2<sup>nd</sup> half of 2016)**
  - Currently, the research about eligible drugs, re-evaluation method is in progress by Health Insurance Review and Assessment Service
  - Based on result of the research and opinions of industry, improvement plans will be discussed

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## NHIS's opinion about raised issues (1/5)

### Mandatory PE data submit for reimbursement

- **RSA is a tool for listing within the principle of Positive List System**
- **PE analysis is possible for most of the risk sharing scheme except for specific type (i.e. CED)**
- **Eligible drugs for RSA and exemption of PE are different**
  - *RSA : necessity of reimbursement*
  - *PE exemption : necessity of reimbursement + possibility of performing PE analysis*
- **Similar methods with weighted ICER, MCDA are used in current decision making process in Korea**
  - *Flexible ICER threshold for anti-cancer/rare disease treatment*
  - *PE exemption for essential drug*

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## NHIS's opinion about raised issues (2/5)

### Refund for patients who pay for the whole cost

- **Necessary to prevent additional burdens of patients due to RSA**  
*\* For the same purpose, NHIS also refunds the difference of co-payment to patients who paid part of the drug cost*
- **The difference between list price and net price should be refunded to patients directly to give benefits to patient who paid additional cost**
- **Until now, possibility of refund rate exposure seems to be low**

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## NHIS's opinion about raised issues (3/5)

### Value Added Tax(VAT)

- **The drug price in Korea is basically including VAT**
  - List price and net price in RSA also include VAT
  - It is reasonable that VAT is included in refund amount to NHIS, because VAT in list price is bigger than that of net price
- **The problem is that company pays VAT to NTS based on list price, even though net price, which is associated with company's profit, is low**
  - Return of VAT relevant to the difference between list price and net price should be discussed with MOSF and NTS

*MOSF : Ministry of Strategy and Finance  
NTS : National Tax Service*

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## NHIS's opinion about raised issues (4/5)

### Operating Expenses

- **Operating Expenses are inevitable to operate RSA**

- Financial Cost**

- Interest cost generated between the period, as NHIS first pay the drug cost at a high price and receive the refund from the company afterward

- Security**

- Safety device to minimize the damage of health insurance finance in case of company's being incapable of refunding to NHIS
    - Adjustable in method of setting security by negotiation(i.e. divided security term)

- **NHIS also bears the cost for administration, labors and establishing IT system for the post-management of RSA**

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## NHIS's opinion about raised issues (5/5)

### Contract Renewal

- **Contract renewal also follows the rule of RSA**

- Only possible when RSA contracted drug is still eligible for RSA
  - If product replaceable or equivalent therapeutic position is available, contract cannot be renewed

- **It would be an excessive favor to first drug, if contract renewal is possible regardless of alternatives**

- The latecomers did not have even chance to apply for RSA

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## Closing Remarks

- **RSA has contributed to improving patients' access to new drug**
- **As a part of the drug pricing system, RSA should be**
  - *operated within the principle of drug pricing system*
  - *in harmony with other drug pricing system*
- **RSA is not a general pathway for listing in Korea**
  - *It is a last resort, not an option*
  - *It is the tool of improving patient access to new drugs, not listing all new drugs*
- **Various factors have to be considered in discussion of RSA**
  - *principle of reimbursement, financial situation, possibility of operation, etc.*
  - *social consensus*

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**Thank you for your attention**