ISPOR 7th Asia-Pacific Conference

HOW CAN RISK-SHARING AGREEMENTS IN KOREA BE IMPROVED?

ISSUE PANELS-SESSION III

TUESDAY, 6 SEPTEMBER 2016, 9:45AM-10:45AM

Moderator

- **Jae-Hyun Lee, PhD**, Professor, School of Pharmacy, Sungkyunkwan University and Korea Regulatory Affairs Professionals Center, Suwon, South Korea

Panelists

- **Hye-Lin Kim, PhD**, Assistance Professor, College of Pharmacy, Sahmyook University, Seoul, South Korea
- **Kevin Haninger, PhD**, Deputy Vice President, International Health Policy, PhRMA, Washington, DC, USA
- **David Grainger,** Director, Global Public Policy, Eli Lilly and Company, Sydney, Australia
- **Nam-Sun Choi,** Deputy Manager, Department of Insurance Benefits, National Health Insurance Service (NHIS), Wonju, South Korea

Overview of Panel Presentation 3

- **Jae-Hyun Lee**
  - Moderator
- **Hye-Lin Kim** ***(20 minutes)***
  - present the results of survey on current status of RSA and improvement directions in Korea.
- **Kevin Haninger** ***(10 minutes)***
  - share global perspectives on the role of RSAs and recent trends.

Overview of Panel Presentation 4

- **David Grainger** ***(10 minutes)***
  - present industry perspective on current Korean RSA system, comparing to Australian RSA system or other countries.
- **Nam-Sun Choi** ***(10 minutes)***
  - share payer's perspectives on the RSA operation and the background of introduction in Korea
- **Discussion & 'Q&A' session with floor** ***(10 minutes)***

Current status of Risk-Sharing Agreements and improvement direction in Korea

Jae-Hyun Lee, PhD
Sungkyunkwan University

Hye-Lin Kim, PhD
Sahmyook University

I. Introduction of RSA

- Detailed operation guidelines for risk-sharing drug-pricing negotiation (NHIS*, establishment 2014.1.21)
  - Risk sharing agreements: A system wherein the drug suppliers share the responsibility for uncertainties regarding the efficacy and/or effectiveness of the drug and the financial impact related to insurance.

* NHIS: National Health Insurance Service

1. Introduction RSA

7

- Difficult to list expensive anticancer drugs, drugs for rare diseases, etc.
  - Proving of cost-effectiveness after positive list system
- Increasing external price referencing
  - Pharmaceutical companies: protect global market
  - Insurers: financial burden, uncertainty of cost-effectiveness.
- Implementation of risk sharing agreement
  - Improve patient access to medication for the four major diseases*
  - Maintain principle of positive list system

* Cancers, Cardiovascular and Cerebrovascular diseases, and Rare diseases

2. Enforcement of RSA in Korea

8

- Enforcement on January 2014
  - As the part of the coverage expansion plan for four major diseases (2013)
- Eligible drugs
  - Anti-cancer or rare disease treatment agents:
    - No alternatives or equivalent therapeutic positions
    - To used to treat serious, life-threating disease; and
  - Other drugs are deemed by DREC* to require negotiation
    - The seriousness of the disease, social impact on health and medical care

* DREC: Drug Reimbursement Evaluation Committee

3. Types of RSA

9

- Conditional Treatment Continuation + Money Back Guarantee
  - Based on individual evaluations after treatment, reimbursement continue for the patients in whom shown the effectiveness while refund to NHIS by the pharmaceutical company
- Expenditure Cap
  - Refund to NHIS a designated rate of the exceeding amount which exceed the annual cap assigned in advance

3. Types of RSA

10

- Refund
  - A designated rate of the amount of total insurance claim for the drug concerned is refunded by pharmaceutical companies to the NHIS
- Utilization Cap / Fixed Cost per patient
  - The limit of use per patient is predetermined, and a designated rate of amount for exceeding the limit is refunded to the NHIS
- Other
  - A different type of sharing plan such as CED, etc. can be suggested

Number of drugs listed through RSA 11

- As of October 2015 (time of survey conducted), 7 drugs

Product	Indication	RSA Type	date
Evoltra(clofarabine)	ALL	CED	2013.12.11
Erbitux (Cetuximab)	Metastatic colorectal CA	Refund	2014.03.05
Revlimid (lenalidomide)	Multiple myeloma	Refund	2014.03.05
Xtandi (enzalutamide)	Advanced prostate CA	Refund	2014.11.01
Xalkori (crizotinib)	Non-small cell lung CA	Refund	2015.05.01
Soliris (eculizamab)	paroxysmal nocturnal hemoglobinuria	Refund	2015.10.01
Pirespa (pirfenidone)	Idiopathic pulmonary fibrosis	Refund	2015.10.03

ALL, acute lymphoblastic leukemia; CA, cancer; CED, coverage with evidence development

Number of drugs listed through RSA 12

- Four more drugs listed as now: total 11 drugs

Product	Indication	RSA Type	date
Caprelsa (vandetanib)	medullary thyroid CA	EC	2015.11.01
Naglazyme (galsulfase)	mucopolysaccharidosis	Refund	2016.03.01
Vimzim (elosulfase)	Morquio A syndrome	EC	2016.06.01
Stivaga (regorafenib)	gastrointestinal stromal tumor	Refund	2016.06.01

CA, cancer; EC, expenditure cap

II. Survey on Current Status of RSA and Improvement Directions

13

- Study Background and Aim
  - With two years of RSA implementation, some opinions about the system in the course of the application and the improvement directions
  - Needs to investigate these opinions for developmental discussion to have this system with more effectiveness
- Subjects of Survey
  - Persons in charge of task regarding drug listing in pharmaceutical companies
    - 117 subjects in a total of 30 companies
  - Government officials (MoH, NHIS, HIRA)

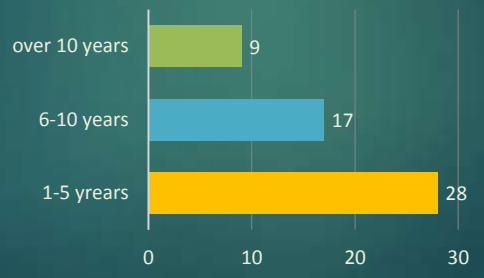
14

- Questionnaire Preparation and Investigation Method
  - Process of Questionnaire Preparation
    - Aug 20, 2015 : In-depth interview of focus group of experts in the industry (Primary)
    - Sep 07-21, 2015 : Preparing of the first draft of questionnaire and pilot test
    - Sep 22, 2015 : In-depth interview of focus group of experts in the industry (Secondary)
    - Sep 22-Oct 08, 2015 : Questionnaire amendment and pilot test
  - Distribution of web-based questionnaires through E-mail

IV. Survey Results

15

- Response Rate
  - Out of 117 subjects who received questionnaires, 54 people (46.2%) responded
- Working career of respondents



Do you have experiences to list new drugs through risk sharing agreement in your company?

16

Response rate: 100.0% (54 responders)

What is the reason that you cannot list the drug as a result despite attempting to list it through RSA?

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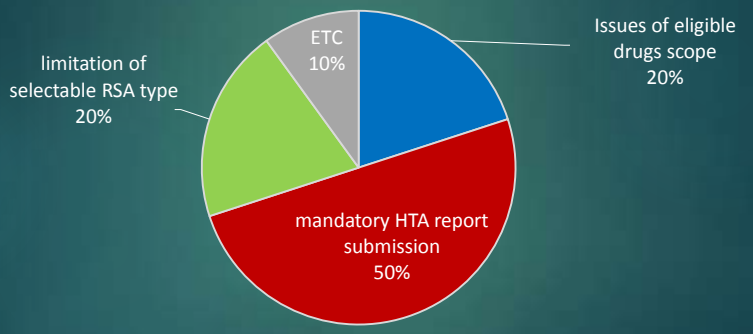

Response rate: 100.0% (10 responders)

In the future, do you (or your company) have a plan to use RSA when listing new drugs?

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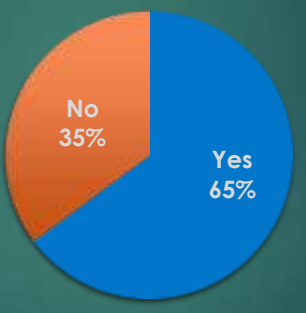


Response rate: 100.0% (54 responders)

Reason why they answer to use RSA in the future

19

- PE is essential for listing of new drugs, but ICER threshold is too low
  - As increasing cost for development, difficult to gain recognition for the value of new drug through the existing PE methods.
  - Issues of comparative alternative in PEs
- Korean drug prices are used as reference price in foreign countries
  - Gap between drug price of development companies and acceptable drug price in Korea
  - Be able to maintain higher posted price than actual price by RSA
- For drugs for rare disease without alternatives, it is expected that the government will request RSA

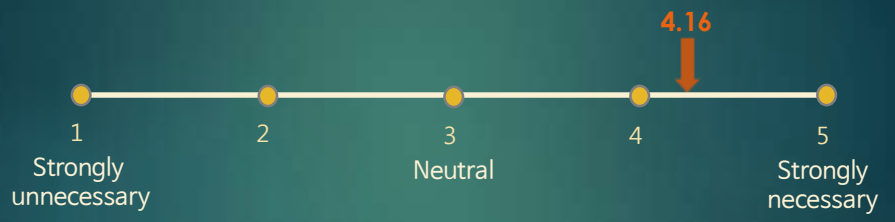
Reason why they answer not to use RSA in the future

20

- Limitation of eligible drugs to the system
- Restriction of reimbursement for expanded indication during RSA and risk of actual price exposure when RSA is terminated
- Concern for exposure of actual price because of refund for patients who pay for the whole medication costs
- Large financial burden on company other than refund cost (interest cost, security, etc.)
- Absence of new drug pipeline

In aspects of necessity of the system itself, on what degree do you feel that the RSA should be maintained? (Scale of 1-5 points)

21



Number of responders(%)				
0 (0%)	5 (9.8%)	6 (11.8%)	16 (31.4%)	24 (47.1%)

Response rate: 94.4% (51 responders)

Do you think that patient's access to new drugs has been improved through RSA?

22

Number of responders(%)				
1 (2.0%)	10 (19.6%)	15 (29.4%)	20 (39.2%)	5 (9.8%)

Response rate: 94.4% (51 responders)

Do you think that RSA is usefully applied as a mechanism for new drug listing under uncertainty?

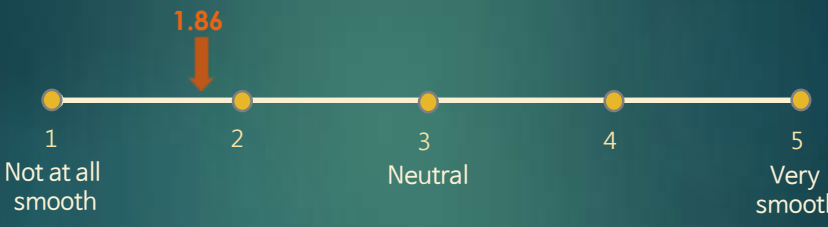
23

Number of responders(%)				
3 (6.1%)	18 (36.7%)	17 (34.7%)	9 (18.4%)	2 (4.1%)

Response rate: 90.7% (49 responders)

In aspects of operation of the system, do you think that the current RSA is operating smoothly?

24

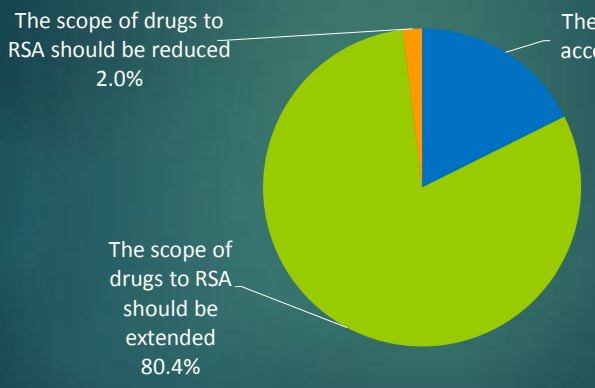


Number of responders(%)				
16 (31.4%)	26 (51.0%)	9 (17.6%)	0 (0.0%)	0 (0.0%)

Response rate: 94.4% (51 responders)

What do you think about the range of eligible drugs for current RSA?

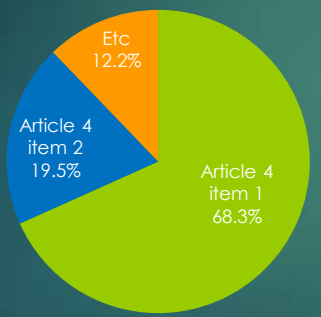
25



Response rate: 94.4% (51 responders)

What do you think is the item necessary to be improved in the current regulations in order to extend the range?

26



Response rate: 100.0% (41 responders)

***Detailed operation guidelines for RS drug-pricing negotiations (Article 4)**

1. Anti-cancer or rare disease treatment agents, for which there are no treatment methods or products that serve as alternatives or are in equivalent therapeutic positions, that are used to treat serious, life-threatening disease; and,
2. Other drugs that are deemed by DREC to require negotiation regarding additional conditions, taking into account the seriousness of the disease concerned, social impact and impact on health and medical care.

Opinion on regulations on follow-up management of RSA

27

Items	Respondents(%)
The current regulation on post management is enough for smooth operation of the system.	0(0.0%)
Specific evaluation guidelines are necessary in order to see which evaluations are conducted for 1 year of evaluation period.	22(50.0%)
Guidelines need to expand the agreement period for specific situation	28(63.6%)
'When alternative or therapeutic equivalent drugs are listed after RSA, it is necessary for the mechanism to renew the system reflecting the situations changed so far	31(70.5%)
The application of extended reimbursement criteria should be allowed during the RSA period.	39(88.6%)
During the RSA period, a mechanism to terminate or amend the agreement under mutual agreement between NHIS and companies.	29(65.9%)
Other	4(9.1%)

Response rate: 81.5%(44 respondents)/multiple answers are allowed

Detailed opinion on improvement plan for f/u management of RSA

28

- Since the drugs listed through RSA are also the ones that receive the assessment of HIRA including PE, etc., reimbursement should be applied to expanded indication like other ordinary cases.
  - In addition, the amendment of the agreement should be allowed reflecting the changed contents.
- Since the effect of drugs considered risk or information on financial influence are accumulated during the RSA period, it is necessary to consider how the new information should be reflected and re-evaluated.
- Even if alternative drugs are listed, it should be possible to extend the agreement, rather than terminating it.

What issues do you think need the improvements regarding refund according to the RSA?

29

Items	Respondents(%)
It is operated favorably by the current regulations.	0(0.0%)
Companies should cover additional cost. e.g. banking cost for refund amount, provision of security, business handling cost regarding refund for patients who pay the whole cost, etc.	40 (95.2%)
Because value added tax (VAT) is included in the amount of refund calculated based on the amount claimed, pharmaceutical companies have to pay VAT redundantly.	39(92.9%)
In the process of returning the amount of refund for patients who pay for the whole cost, there is possibility of violating confidentiality of the content of the RSA.	38(90.5%)
Other	1(2.4%)

Response rate: 77.8%(42 respondents)/multiple answers are allowed

What is your opinion on handling of the amount of refund for patients who pay for the whole cost?

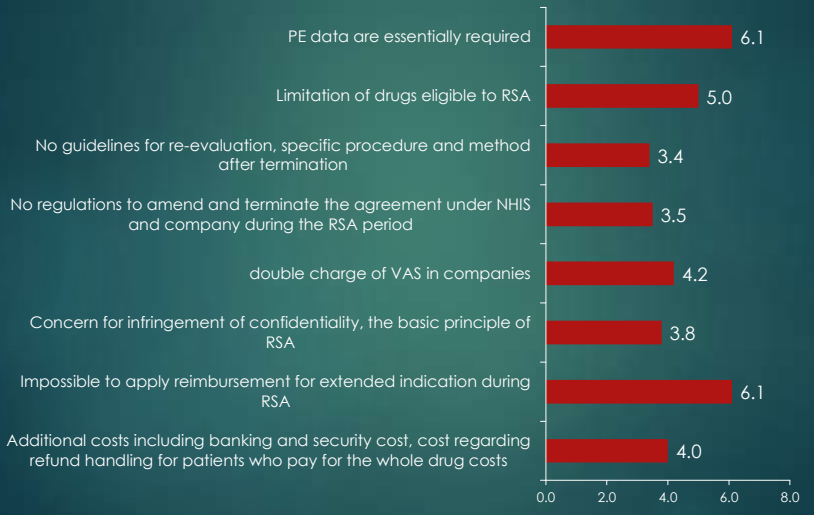
30

Items	Respondents(%)
Because a doctor prescribed after acquiring consent of patients for the coverage of the whole cost, refund to the patient is not necessary.	18(47.4%)
It is not necessary to refund the amount to the patient directly, but the refund system should be used as a method to give benefit to patients with the applicable diseases.	18(47.4%)
Other	2(5.3%)

Response rate: 100.0% (38 responders)

Evaluation of priority on improvement necessity

31



Response rate: 77.8% (42 responders)

IV. Result summary and Limitation

32

1. **Summary of Results of Survey**

- The pharmaceutical industry has consensus for need to maintain RSA.
  - Despite the small number, drugs that could not be listed under the previous drug pricing system were reimbursed, and the access was evaluated to be improved partially through the RSA
- However, there were some negative evaluations for the operation of the system.
  - Subject of application for RSA
  - Problems in the process of post management: re-evaluation, refund, etc.

33

1. **Summary of Results of Survey (cont'd)**

- Especially, it was investigated that the following items needed a lot of improvement.
  - Impossible to apply extended reimbursement indication during RSA period.
  - PE data are essentially required like ordinary new drugs.
  - Limitation of subjects of application for RSA
  - VAT double charge and additional cost for refund amount calculated with the amount claimed

34

2. **Limitation**

- The survey did not include all related concerned parties on introducing the new drug
  - performed only for the pharmaceutical industry.
  - In the present, the government is in the process of providing the revised plan on the issue regarding the RSA, therefore did not participate on the interview and the survey.

V. *Topics to discuss the way how RSA could be improved*

35

- Like all drug price systems, the RSA must also be discussed on the role and function of the relevant system in the overall view of the drug pricing system.
  - Drugs characteristics: public goods & general goods
- Consideration various factors for drug pricing system
  - Sustainability of the insurance finance
  - Ensuring therapeutic accessibility of the patients, and
  - Acceleration of R&D by pursuing fair profit

36

- Issues that discussed frequently 1: mandatory PE data submit for reimbursement
  - PE represented by ICER is most widely used tool to evaluate efficiency
  - Drugs for rare diseases or severe diseases: difficult to prove clinical benefit and cost-effectiveness
- Newly decision making tools such as MCDA (Multiple-criteria decision analysis) and weighted ICER (method of considering the social value on applying the ICER threshold)

37

- Issues that discussed frequently 2: expanded indication before termination of RSA
  - Instead of operating the drug pricing system in an administrative (regulatory) ways, discussion between the concerned party of the health payer and the pharmaceutical company must be made in a 'negotiation' ways.

38

- Government side's opinion through two forums in 2015
  - Among eight newly listed drugs through RSA, four were listed without PE ICER. PE should be maintained as the most important principle in drug pricing system, but it could be applied mitigatedly in the cases of essential drugs or correspond to CED.
  - According to the restriction of expanding the coverage during the agreement period, the review will be done on even the parts requiring revision of related law.

39

Thank you for your attention!