THE EUROPEAN CHAMBER OF COMMERCE THAILAND

Sustainable Healthcare Financing solutions

Risk-Sharing Agreement Proposal for sustainable health system and patient access in Thailand

European Association for Business and Commerce proposal for Sustainable Healthcare Financing Solution, Risk-sharing Agreement

Having adequate and sustainable healthcare financing is one among key enabling factors to ensure a greater chance of success in innovation development as a key engine to drive country economy, due to the market environment. It is important that the government manage to have appropriate and adequate sources of funding since increasing chronic diseases and life expectancies associated with an aging population tends to drive overall healthcare expenditures up. This will also ensure sustainable access to healthcare, treatment outcomes and quality of life for patients, which require public and private efforts to provide alternative and collaborative solutions in long term.

The European healthcare industry experienced similar challenges in the other government agencies including in the European countries, which we also experienced some solutions to bring that for benefit of Thailand development like alternative access models, innovative and value-based financing models, as well as promoting self-care policy as the contributing solution to promote sustainable healthcare financing. This could support the sustainable system development to enhance patient access for pharmaceuticals and medical devices and government budget management.

Moreover, the market environment would be another key enabling factor for innovation and attracting the investment for innovation development for economic growth, establishment of the solution for sustainable healthcare financing could additionally support the investment promotion through improvement of innovation-friendly ecosystem encouragement.

European Association for Business and Commerce (EABC) would like to submit the proposal to contribute and enhance sustainable healthcare financing in two key aspects:

1. **Enhance efficiency in the existing system:**
   - 1.1 Exploring Risk-sharing/ Manage-Entry Agreement for innovative medicines i.e. cancers, rare diseases and medical devices
   - 1.2 Incentivizing self-accountability in health (self-care) i.e. self-care incentive, health insurance incentive through taxation program
   - 1.3 Ensuring reimbursement and facilitating procedures for digital intervention

2. **Revisit core financing model to upgrade the system:**
   - 2.1 Utilizing Sin Tax – budget management i.e. reinvesting into healthcare program (vaccination, early diagnosis to enhance early treatment option for cost efficiency, other health promotion)
   - 2.2 Options beyond traditional financing – earmarked schemes (e.g. cancer fund), individual health savings accounts, social impact bonds, crowdfunding
   - 2.3 Additional supplementary health package

Proposal of Risk-sharing or Manage-Entry Agreement to enhance efficiency in the health system

EABC experiences an establishment in other countries that Risk-sharing/ Manage-Entry Agreement as Public-Private Collaboration could be one of the key elements to ensure sustainable healthcare investment as "**alternative/innovative mechanisms that the private company shares the financial risks at the national level with the government on patient treatment costs".** This can support patient access and treatment needs as well as the government budget can be predictable and manageable to achieve superior health outcomes at the same or reasonable incremental costs**.** An example and key points could be highlighted as below:

South Korea: The South Korean government adopted the positive listing system for new drugs to allow for more rational management of drug expenditure. Price–volume agreement system was on among other mechanisms implemented to manage drug use. Under this system, the prices for drugs whose use increased by 30–60% were reduced by up to 10% according to an agreement between the National Health Insurance Service (NHIS) and the pharmaceutical companies. The South Korean government implemented the risk-sharing agreement system in December 2013. Under this system, the government and pharmaceutical companies share uncertainties regarding the clinical outcomes of new drugs and their influence on the budget, thereby making it easier for drugs to be listed. This risk-sharing agreement system was implemented to adhere to the positive reimbursement of cost-effective drugs while also improving patient access to new drugs and promoting the development of the pharmaceutical industry; it is particularly relevant for cases.

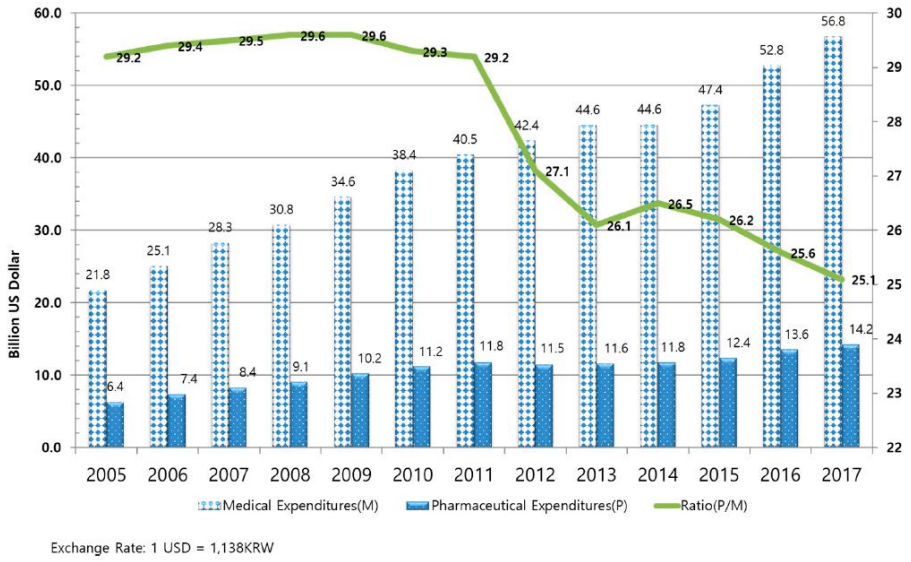


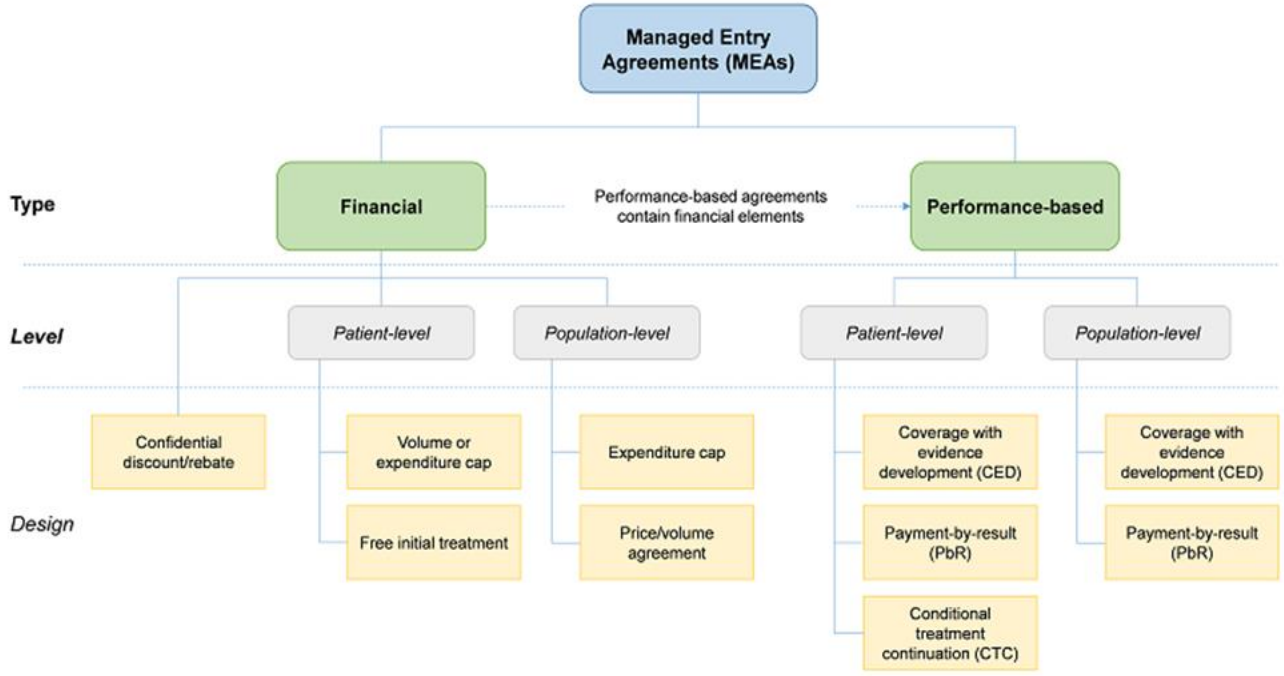
Figure 1. Trends in pharmaceutical expenditures in the South Korean national health insurance. Source: National Health Insurance Service, 2017 Healthcare expenditures, document number:11-B550928-000036-08.

Value for budget management through Risk-sharing Agreement/ Manage Entry Agreement Models

(1) Enabling the introduction of new and costly medicines into the reimbursement system in a better-controlled way
(2) Increasing and improving patients' access to medicines and other products as the needs of treatment
(3) Enhancing financial sustainability of the reimbursement system and cost predictability since it creates direct saving and predictable incremental budget

(4) Increasing flexibility of shaping the pricing and reimbursement policy

According to international experiences, there are various types of Risk-sharing/ Manage-Entry Agreement as followings under the two major types as Financial based agreement and Performance based agreement:



For Thailand's context, there has been partial adoption of the principle of the risk-sharing/ managed-entry agreement to the public healthcare reimbursement schemes for universal health coverage, a national list of essential medicines, and a civil servant medical benefit scheme on the oncology prior authorization. The example can be highlighted as the implementation of the capitation model which the companies shared the financial risk by providing medicines, free of charge, to patients according to the agreed capitation threshold. However, such implementation remained constraints, especially in the administration of the medicine reconciliation between the payer, hospitals, companies, and patients.

If we aim to enhance the utilization of risk-sharing/ managed-entry agreements in Thailand to cover broader scopes of models in similar to other countries, i.e. rebate and refund models, it will require consideration and justification of the legal feasibility to ensure compliance, transparency, and monitoring.

EABC would like to propose the **Proposals for Risk-sharing Agreement/ Manage Entry Agreement Models for Thailand** with key requirement for consideration as follows.

The diagram summary of each model is showed in Annex I:

Proposed models	Definition	Benefits	Proposed requirements/ regulations to facilitate model establishment
1. Financial-based agreement			
Refunds (rebates) (Expenditure caps refunds after the cap/ utilization caps per patient)	Simple rebates/ refunds, publicly or confidentially agreed upon between the payer and manufacturer.	Simple and proven effective way to reduce prices and budget impact	• Refund/ rebate as monetary base – This will need regulation to support the acceptance of refund/ rebate or evaluation of feasibility under current system 1. National/ Payer level or 2. Hospital level (benefit will be at hospital level/ not payer saving) • Refund/ rebate as free medicine – 1. Payer level – process on payer handling of free medicine rebate usage/ distribution to be clarified 2. Hospital level – free medicine rebate benefit will be at hospital level/ not payer saving • Need establishment of registry & tracking system on: - Usage of medicines - Free medicine supply
Discounts (%of discount for an agreed treatment of cycle or lowering reimbursement/ procurement price after reaching agreement/ by result)	Simple discounts, publicly or confidentially agreed upon between the payer and manufacturer.	Multi-year contract in supporting discount agreement will benefit drug supply security	• National/ payer/ hospital levels – Feasibility under Procurement Act should be clarified • Multi-year contract could support implementation of discount agreement as increasing volume yearly • Need establishment of registry & tracking system (procurement/ reimbursement) on: - Usage volume

Proposed models	Definition	Benefits	Proposed requirements/ regulations to facilitate model establishment
Capitation: 1. **Expenditure caps (per medicine or per total treatment) + free doses** 2. **Utilization caps per patient + free doses**	Maximum amount of spending for an individual innovative treatment (budget threshold) or therapeutic area (dedicated funds) to contain total expenditures. Translates into maximum number of patients treated per year or sharing of costs with the manufacturer or patients after costs have been exceeded.	Straightforward way of limiting total drug expenditure while allowing access to innovative medicines Knowledge of potential maximum returns may Incentivize manufacturers to be more tactical in choosing their investments, improving efficiency of the industry Dedicated funds can provide patients with access to therapies they would not have had otherwise	• Need establishment of registry & tracking system on: - Patient registry & tracking - Usage of medicines - Free medicine supply
Free initiation			• Need establishment of registry & tracking system on: - Patient registry & tracking - Usage of medicines - Free medicine supply
Price Volume Agreement	Drug prices are progressively lowered as more patients receive the treatment.	Places a limit on maximum expenditure per drug while ensuring availability to patients Effective cost-control mechanism when limited measures are available to prevent off-label prescribing	• National/ payer/ hospital levels – Feasibility under Procurement Act should be clarified • Multi-year contract could support implementation of discount agreement as increasing volume yearly • Need establishment of registry & tracking system on: • Usage volume

Proposed models	Definition	Benefits	Proposed requirements/ regulations to facilitate model establishment
		or prescribing in populations where the drug will be less cost effective	
2. Performance-based agreement			
Refunds, (rebates)/ (upon disease progression)	The price level and/or revenue received is related to the future performance of the product in either a research or real-world environment. Therapy costs are eliminated or reduced by the manufacturer if outcomes are not achieved.		• Refund/ rebate as monetary base – need regulation to support the acceptance of refund/ rebate or evaluation of feasibility under current system 1. National/ Payer level 1. Hospital level (benefit will be at hospital level/ not payer saving) • Refund/ rebate as free medicine – 1. Payer level – process on payer handling of free medicine rebate usage/ distribution to be clarified 2. Hospital level – free medicine rebate benefit will be at hospital level/ not payer saving • Need establishment of registry & tracking system on: - Usage of medicines - Free medicine supply

<u>Development of Data Registry for Risk Sharing/ Manage Entry Agreement:</u>

Referring to experience in other countries, data registry benefits for transparency of information and monitoring appropriate use, which will capture drug usage, and patient outcomes.

Italy is one of the countries with effective data registry. The Italian Medicine Agency (AIFA) Registry is part of the reimbursement landscape. It was set up in December 2005. There is different level of data accessibility. Physicians and pharmacists can access to patient data level but only to their own while payer can access national overview of aggregated anonymized data for drugs and indications. Pharmaceutical companies can also access a national overview of aggregated anonymized data only for their drugs.

The registration of the patients in the AIFA Registry is mandatory to get the reimbursement of the drug by National Health Service. The objectives of the registry are:

- Monitoring appropriate use of drugs according to approved therapeutic indications
- Assessing and tracking patient eligibility
- Evaluating utilization in clinical practice
- Collecting epidemiological data including safety profile

Data Fields in AIFA registry

Form	Collected Data	Responsible
1. Registration	Mandatory for every new patient enrolled in the treatment. It includes specific information about age, gender, Region of birth and hospital in which the patient is intended to undergone the treatment regimen, as well as name of the treating physician and date of enrollment of the patient	Physician
2. Diagnosis	Specific for every oncology drug, and for every indication approved and inserted in the monitoring system	Physician
3. Request	It has to be filled by the treating physician in order to point out the expected daily and total dosage within the treatment regimen	Physician
4. Dispensation	Compiled by the hospital/territorial pharmacy	Pharmacists
5. Follow Up	Re-assessment of the disease progression in order to identify the responder patients	Physician
6. End of Treatment	It reports the details of every treatment suspension reasons	Physician

The monitoring is web-based and allows the physician to issue an electronic request for a precise dose of the drug regarding a patient whose diagnosis corresponds to the parameters of the authorized therapeutic indication (Fig. 1). The electronic form application, valid for a single administration, is automatically sent by email to the hospital pharmacy, which proceeds to close the form by formally and practically dispensing the requested drug. The system is accessible from any computer connected to the internet through the use of a username and password.

In addition, and not least, is very important also to analyse the use of the innovative therapies directly with the pharmaceutical companies, according to the principle of risk sharing or pay by result: the

awareness and evaluation of results of clinical practice and the purpose of defining the right cost to be incurred by the national health system.

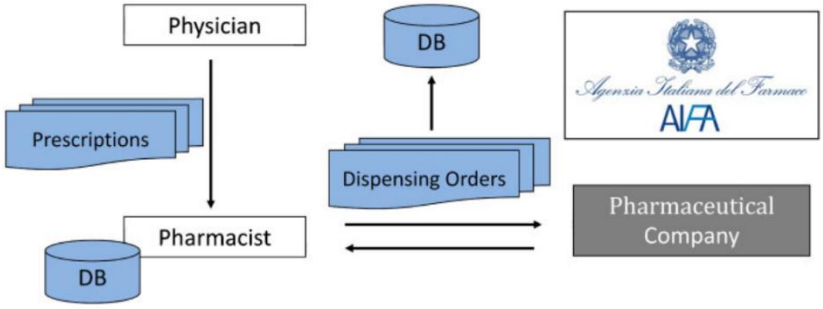


Figure 1 Patients' case report forms must be filled in, in a specific web-based monitoring register (RFM). The register tracks the eligibility of the registered patients and the complete flow of the treatments

Proposals for consideration in sustainable healthcare financing management through an establishment of Risk-sharing/ Managed-entry Agreement:

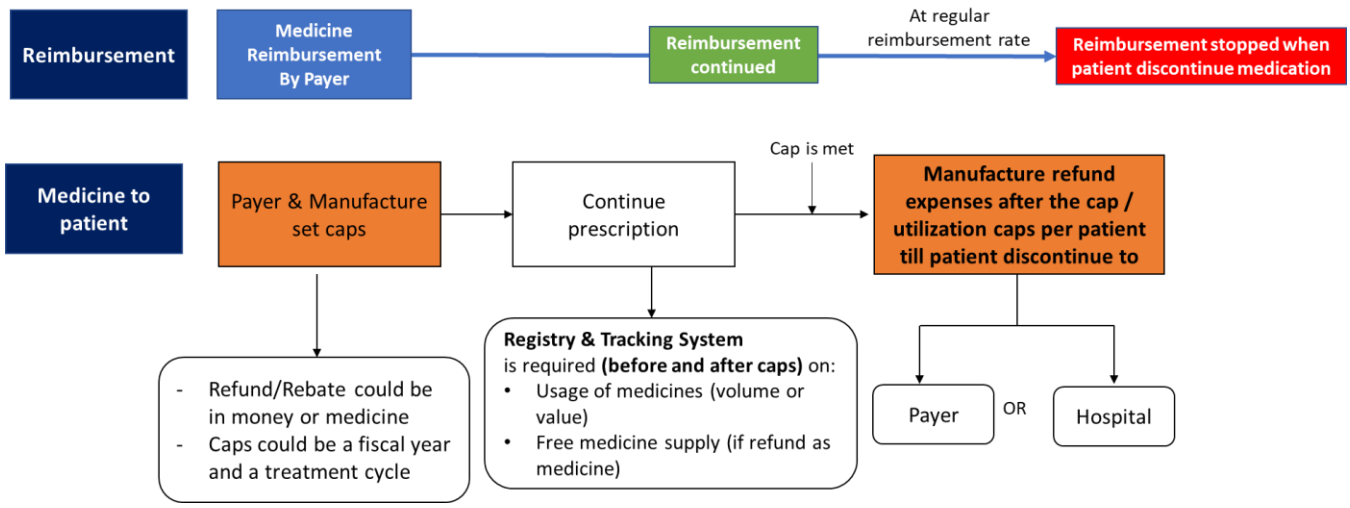
- EABC would like to support and collaborate on the development of "risk-sharing" framework and proposed key requirements and registry for consideration in an establishment to benefit patients and government management:
    - Policy and regulations related to procurement and reimbursement to enable "risk-sharing" reimbursement for patient access as proposals
    - Explore feasibility in the establishment of Confidentiality agreement for risk-sharing implementation under Thailand contexts
    - Development of the data registry and system for reconciliation, tracking and data sharing platform for reimbursement (between payer, hospital and company)

ANNEX I

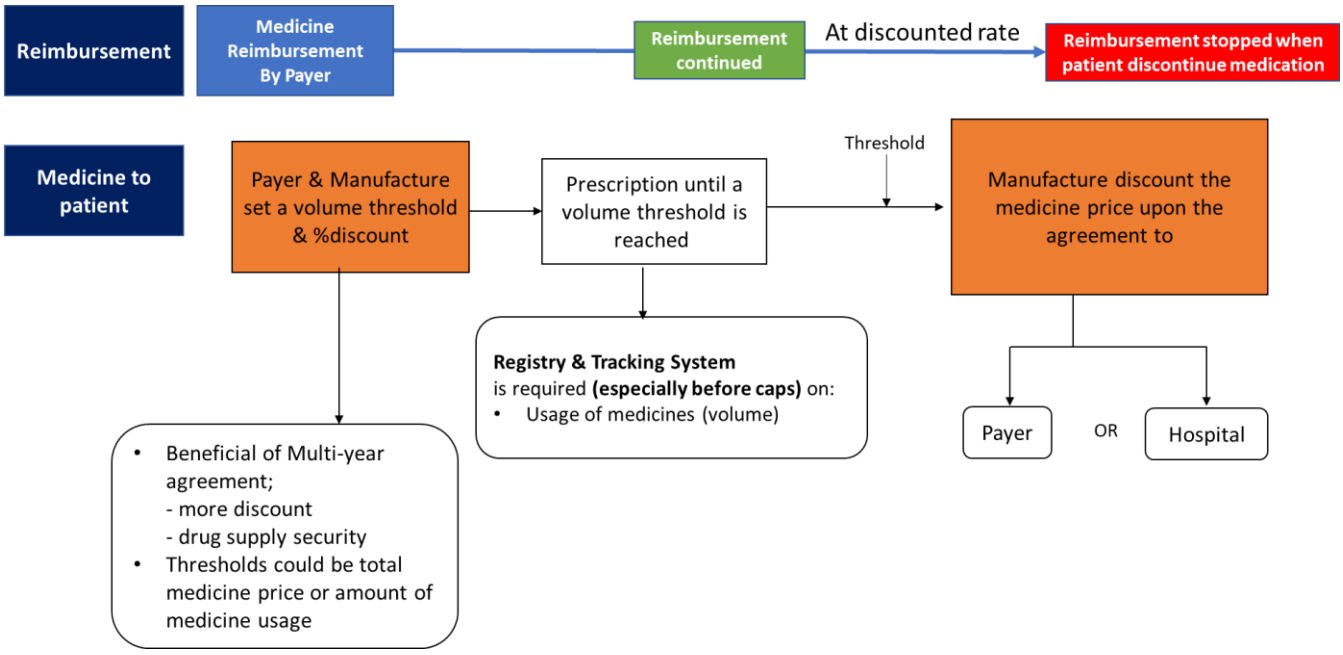
Summary of Risk-sharing Agreement/ Manage Entry Agreement Models for Thailand

1. Financial-based agreement

1.1 Refunds (Rebates) (Expenditure caps as monetary basis/ or free medicine)



1.2 Discounts (%of discount for an agreed treatment of cycle or lowering reimbursement/ procurement price after reaching agreement/ by result)



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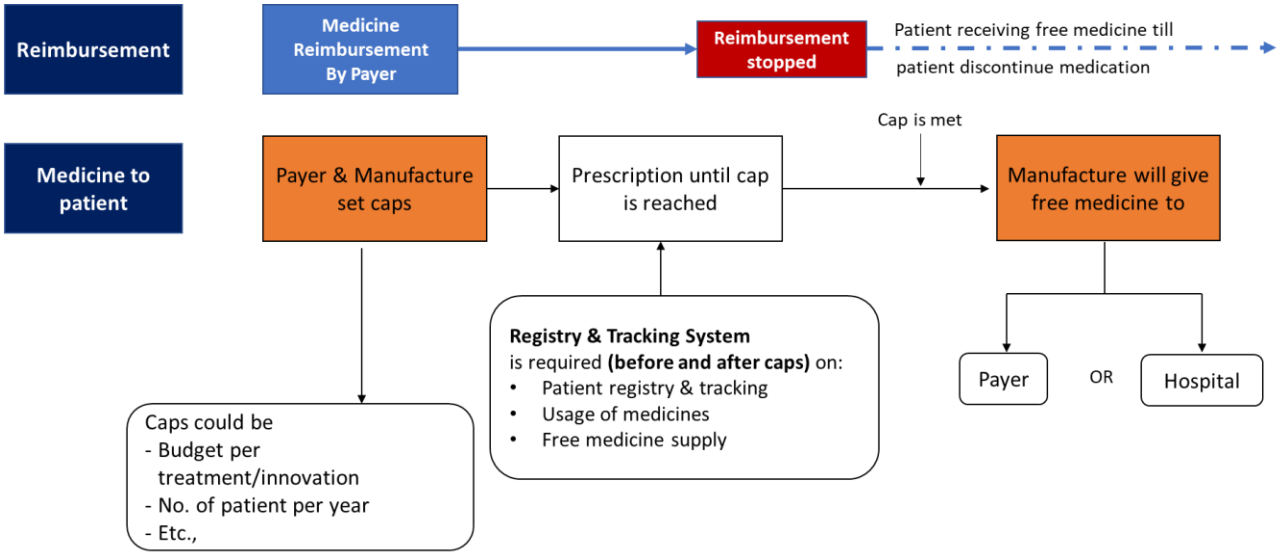
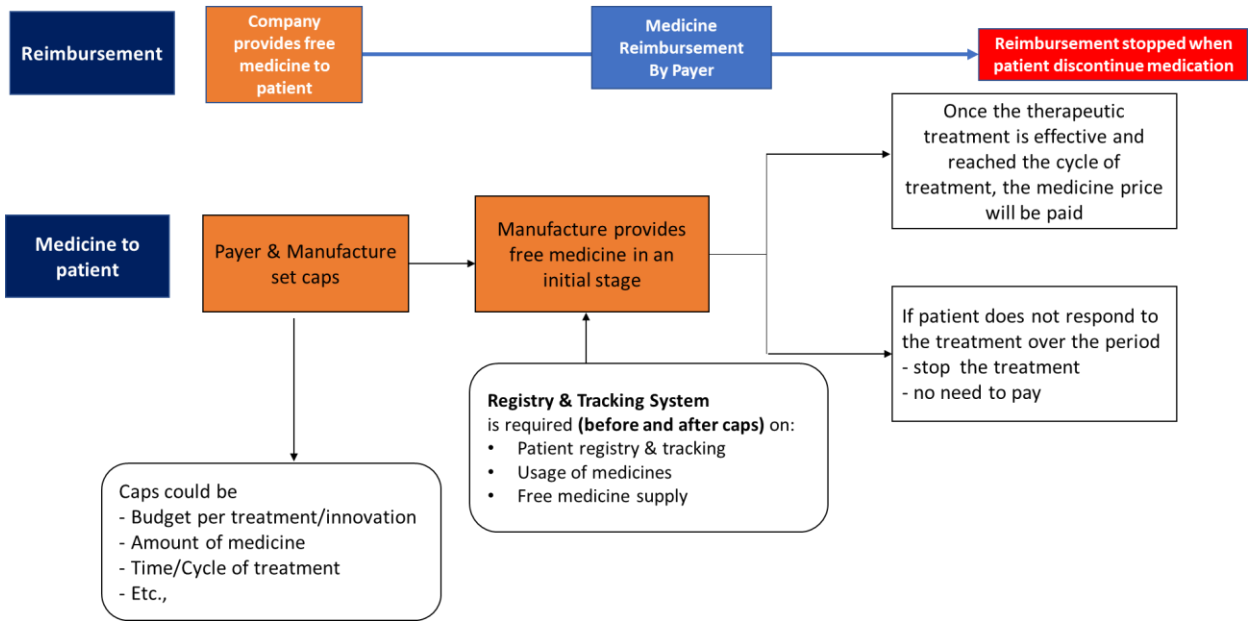
An Initiative Supported by the European Union

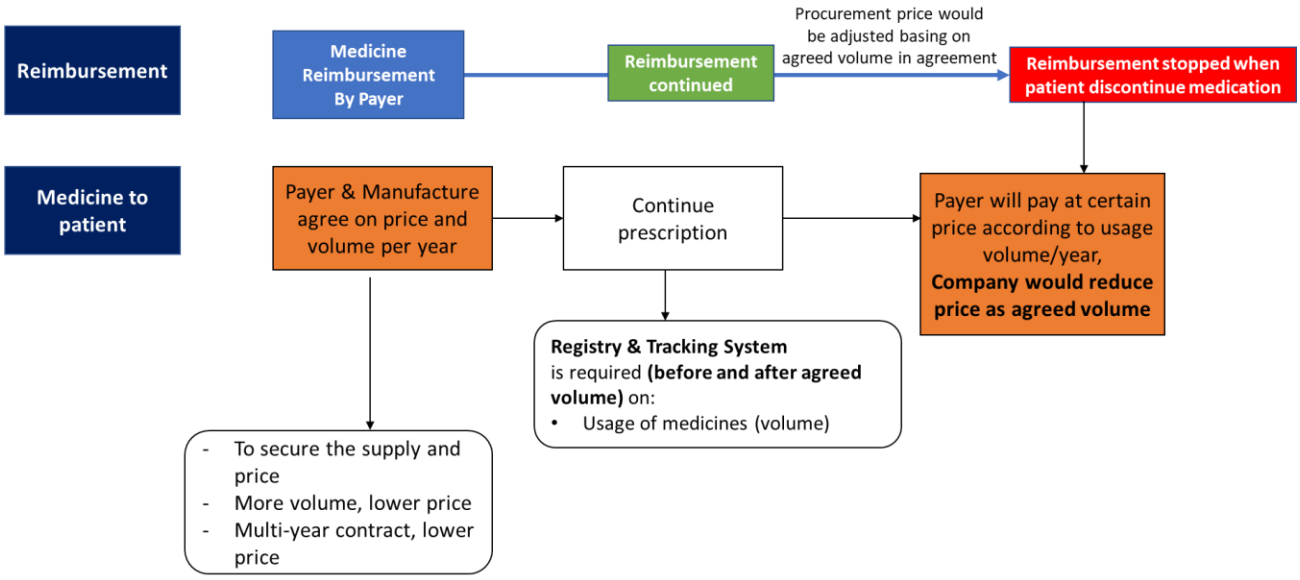
1.3 Capitation



1.4 Free initiation

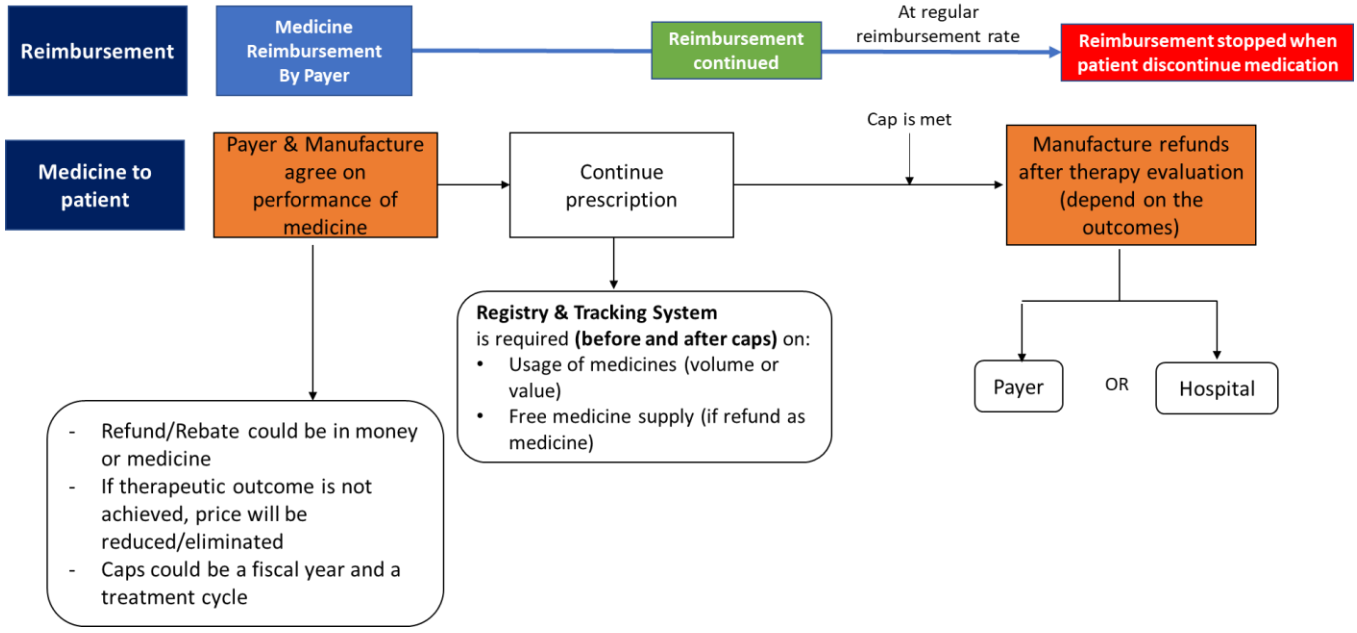


1.5 Price Volume Agreement



2. Performance-based agreement

2.1 Refunds / Rebates as monetary basis or free medicine (upon disease progression)



ANNEX II

Glossary

Abbreviation	Full terminology
AIFA	Italian Medicines Agency
CED	Coverage with Evidence Development
CTC	Conditional Treatment Continuation
EABC	European Association for Business and Commerce
MEA	Managed-entry agreement
NHIS	National Health Insurance Service of the Republic of Korea
PbR	Payment-by-Result
RSA	Risk Sharing Agreement