

ENHANCING MUTUAL STAKEHOLDER BENEFITS IN SELF-CARE MEDICINE REGISTRATION



PANEL MEMBERS

Moderator

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SET THE SCENE FOR DISCUSSION

Prospective of self-care regulation
(declaration in 1st self-CARER in 2014)

*To expedite the launch of high-quality OTC
medicines for Asian consumers*

Prospective of self-care regulation

1. Active ingredients of OTC medicines must have the experience/evidence of safe and efficacious use in prescription or OTC medicines, and the safety and efficacy of OTC medicines must be confirmed. Considering the lower level of risk in OTC medicines, the assessment process for OTC approval should be different from the assessment process of new ethical medicines.
2. The Investigation of the registration requirements should be conducted to optimize the data required for OTC medicines approval in each country, and avoid the unnecessary repetition of data generation to support the registration, particularly clinical studies.
3. OTC medicines which active ingredients are listed in the monograph and/or have the experience/evidence of use in other countries, which active ingredients have evidences of safety and efficacy, and which active ingredients do not exceed the dosage and application in other countries, should be regarded as the “**well-established OTC medicines**” and the minimum approval requirements should be adopted by the regulatory authority (e.g. ANDA or generic drug application, instead of NDA or new drug application).
4. The appropriate use of Brand names in OTC medicines should be authorized, given it help in communicating the characteristics of OTC medicines, and avoiding the misapplication use.
5. Tabular list of ingredients/dosages approved for OTC medicines in each country (Asian version monograph) should be established, and health authorities should explore the harmonization possibility to allow the common classifications, ingredient, doses etc. in OTC medicines within Asia.
6. Efforts should be made to achieve optimization of OTC approval assessment through interaction between regulatory authorities of individual countries, and ultimately the cooperation between authorities in driving the regulatory optimization or harmonization in OTC registration across Asia.

DISCUSSION POINTS

- What is the level of self-care awareness in your country? –all 4 countries

DISCUSSION POINTS

- What is current status of OTC registration /regulation in your country, after the 1st RTD meeting in Phuket in 2014? Any new regulation or changes? - all 4 countries

DISCUSSION POINTS

- What is the top priority that country should work to get full benefit of self-care? – all 4 countries + APSMI

DISCUSSION POINTS

- What is the role of “APSMI/industry” and “government” help drive the self-care policy? – APSMI

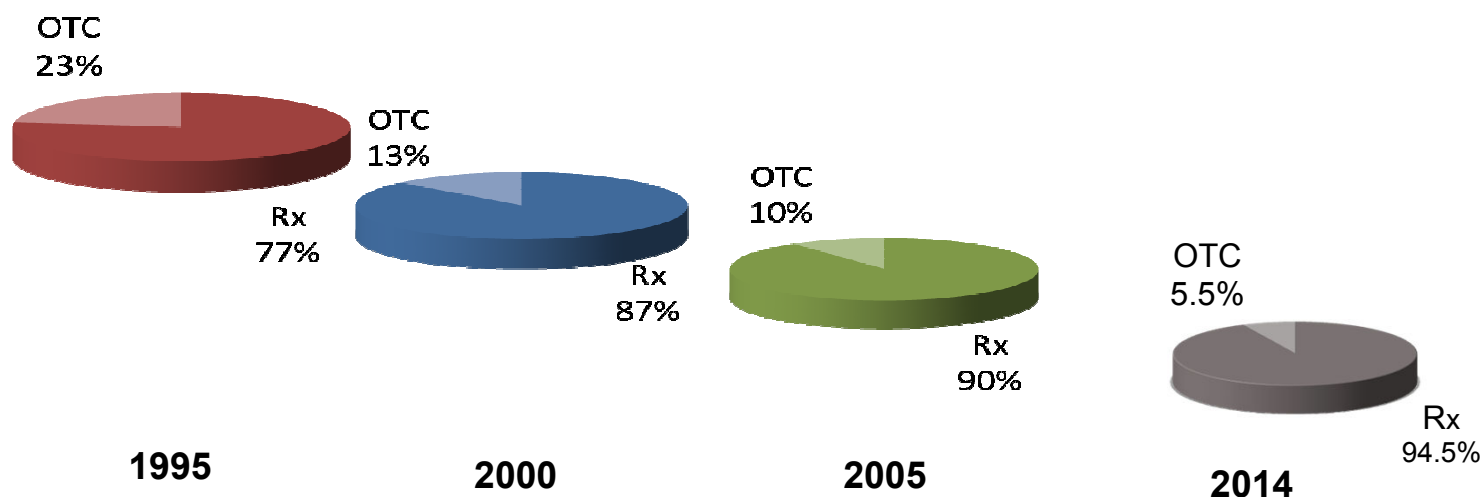
BACK UP SLIDES — TAIWAN & JAPAN



Level of Self-care awareness in Taiwan

In developing

- Consumers are with high health consciousness: 84% of general public in Taiwan are willing to maintain regular self health care.
- High National Health Insurance (NHI) coverage, low self-medication (34%)
- Different expectation for self-care/ self-medication among stakeholders



Regulatory progress after 1st RTD meeting

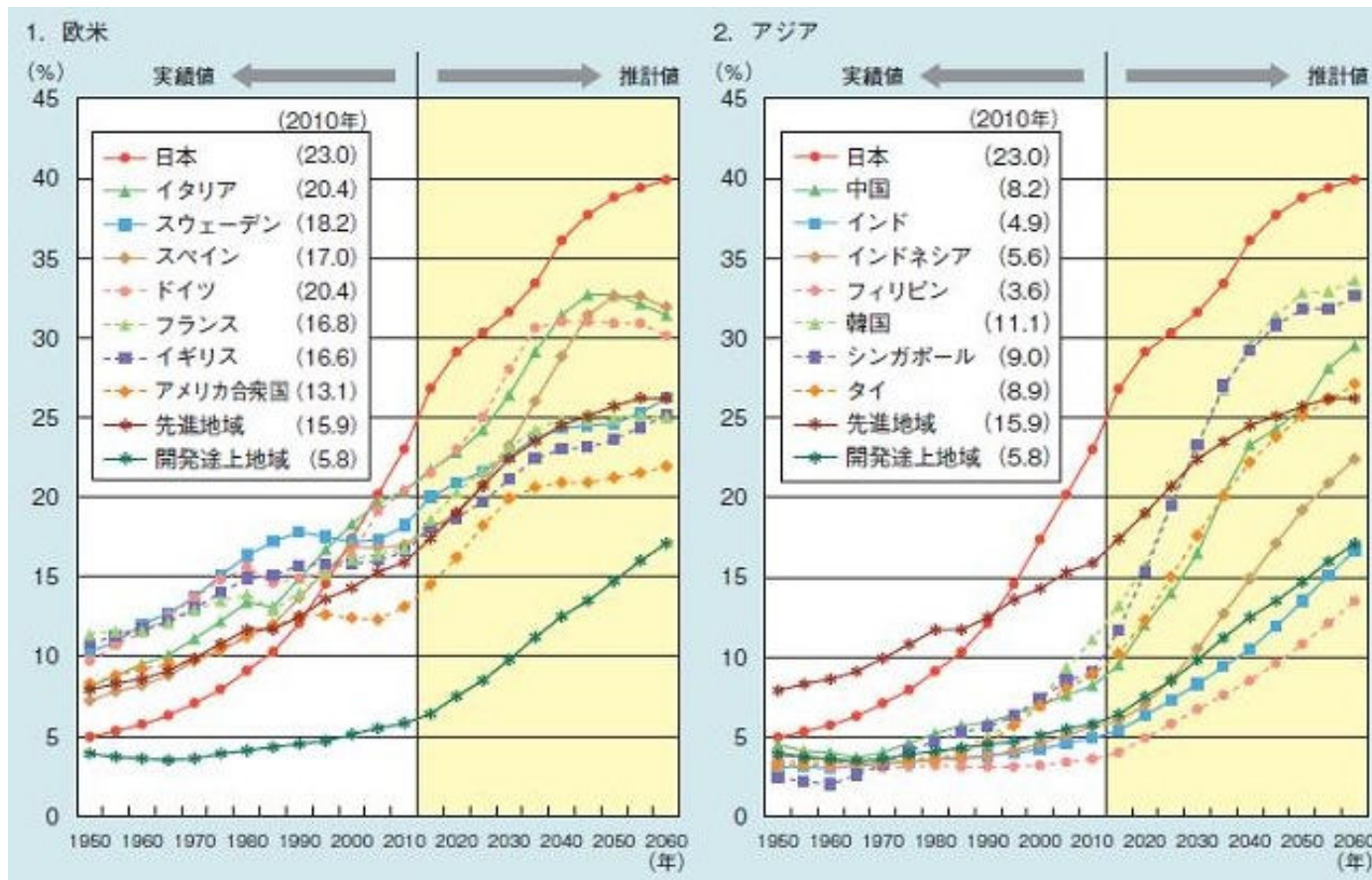
- Completed monograph revisions:
 - Newly add 3 categories:
 - Anti- hemorrhoids preparation (draft version)
 - Anti-Acne preparation (draft version)
 - Topical steroid preparation (draft version)
 - Revision on the current monograph:
 - Ophthalmic preparation (Final version)
- TFDA showed its determination in Rx-to-OTC switch in Jan → been strongly against by the physician association
- Complete the review for 6 ingredients for Rx-to-OTC (to be published to industry by end of Oct)
- Host an International OTC workshop
 - Introduce best practice from other markets to Taiwan stakeholders
 - Set up a platform for stakeholder communication

Top Priority for self-care in Taiwan

- Continue the efforts in establish switch mechanism and cases
- Strengthen the role of community pharmacists
- Get alignment within stakeholders to drive consumer empowerment

Global Trend of Aged

(figures for 2011 and later are estimated value.)

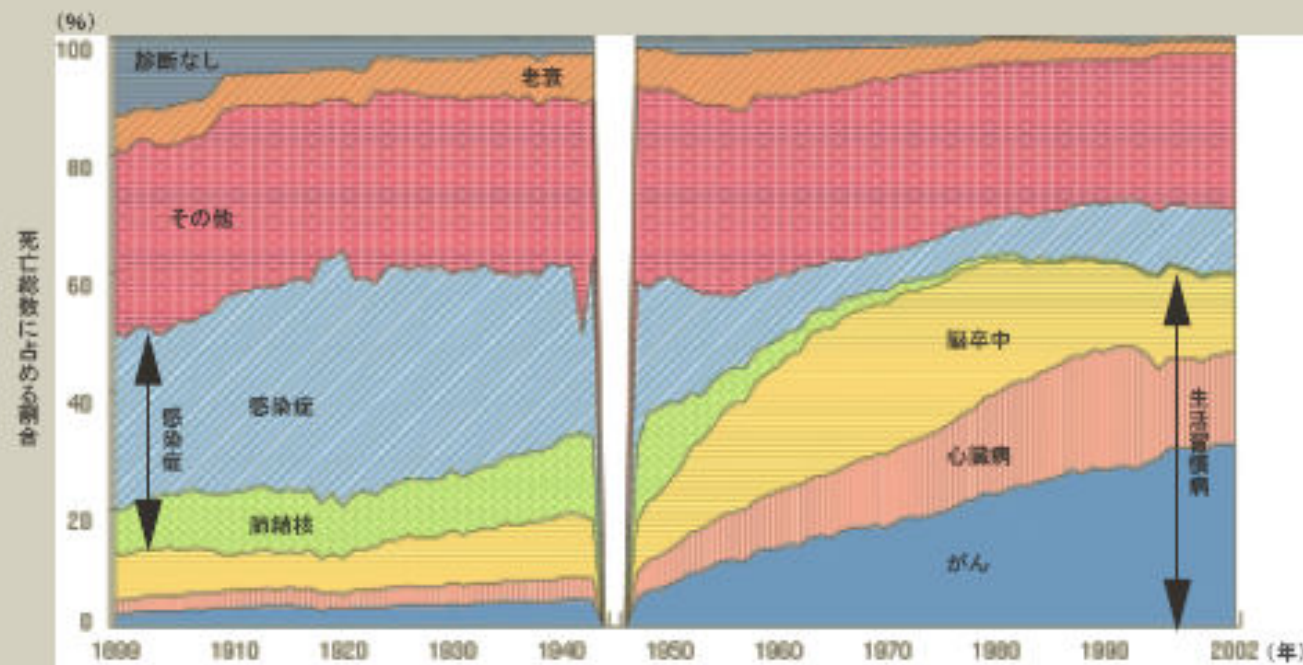




Before the WW II, Infectious diseases killed young and aged. After the WW II, Life-style diseases gave us more heavy burden.



図表序-8 我が国の20世紀の死亡に関する疫学的変遷

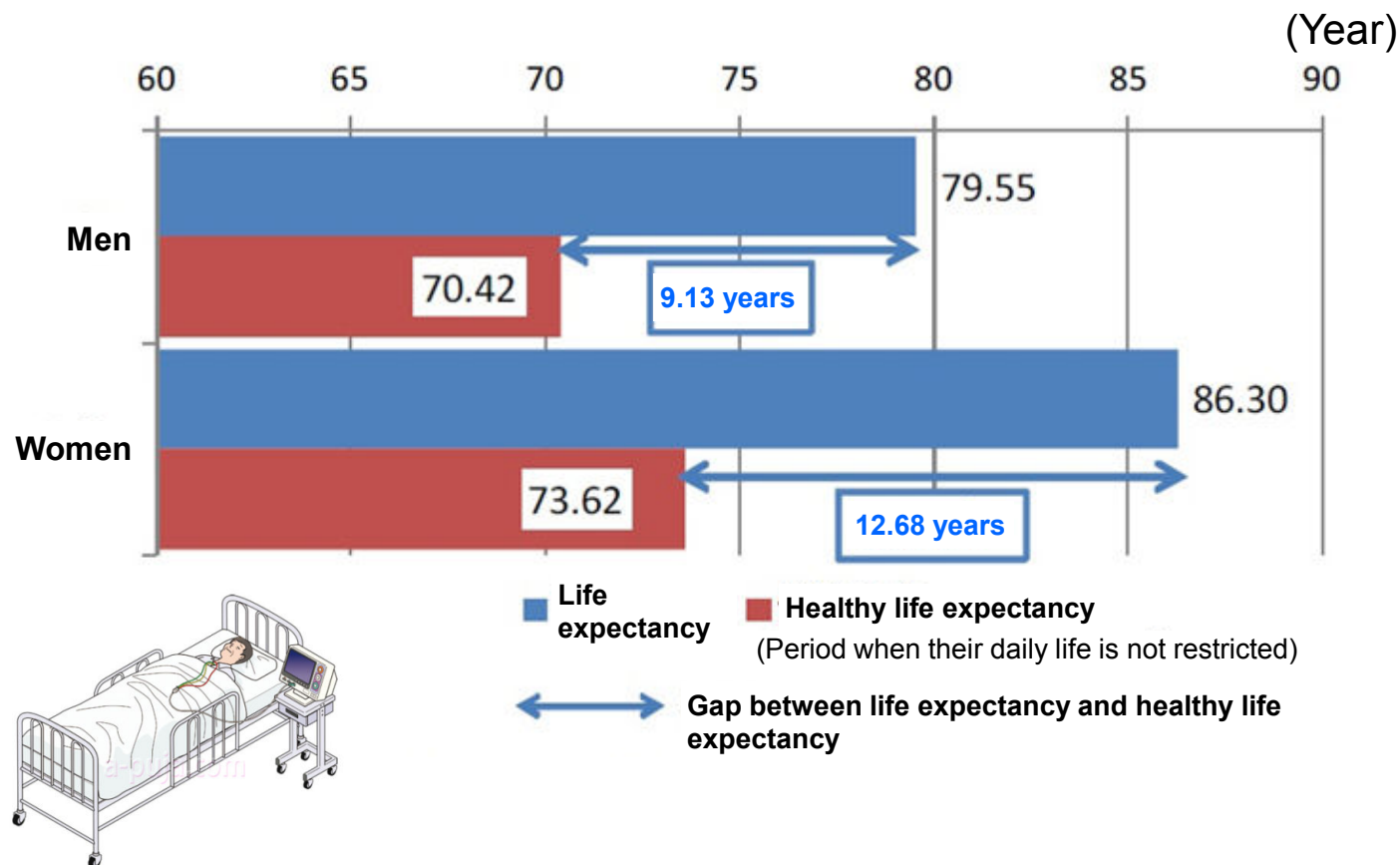


資料：厚生労働省大臣官房統計情報部「人口動態統計」より作成

From 2004 MHLW Year book



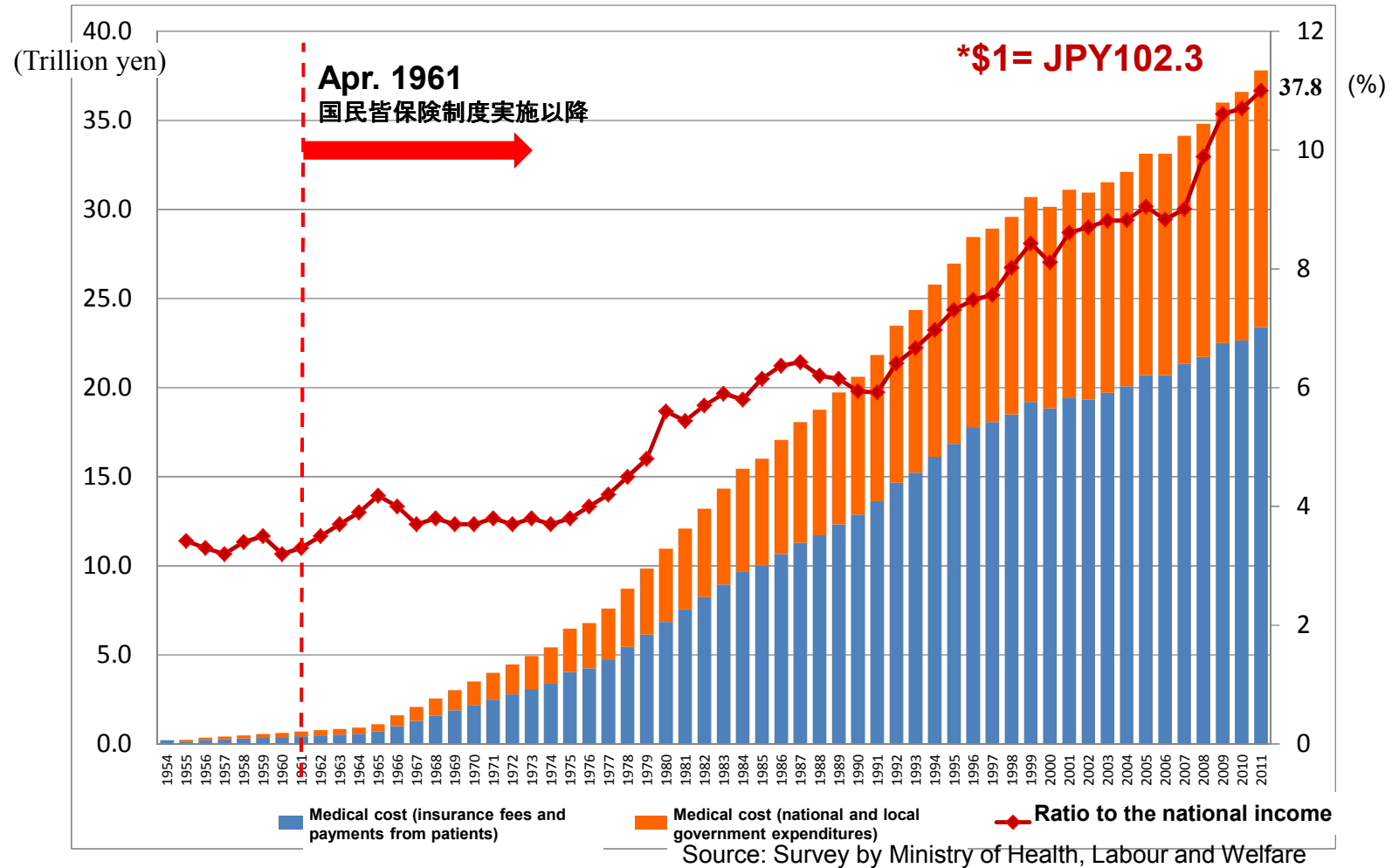
Gap between “life expectancy” and “healthy life expectancy”



Source: A survey conducted by Ministry of Health, Labour and Welfare (2000)

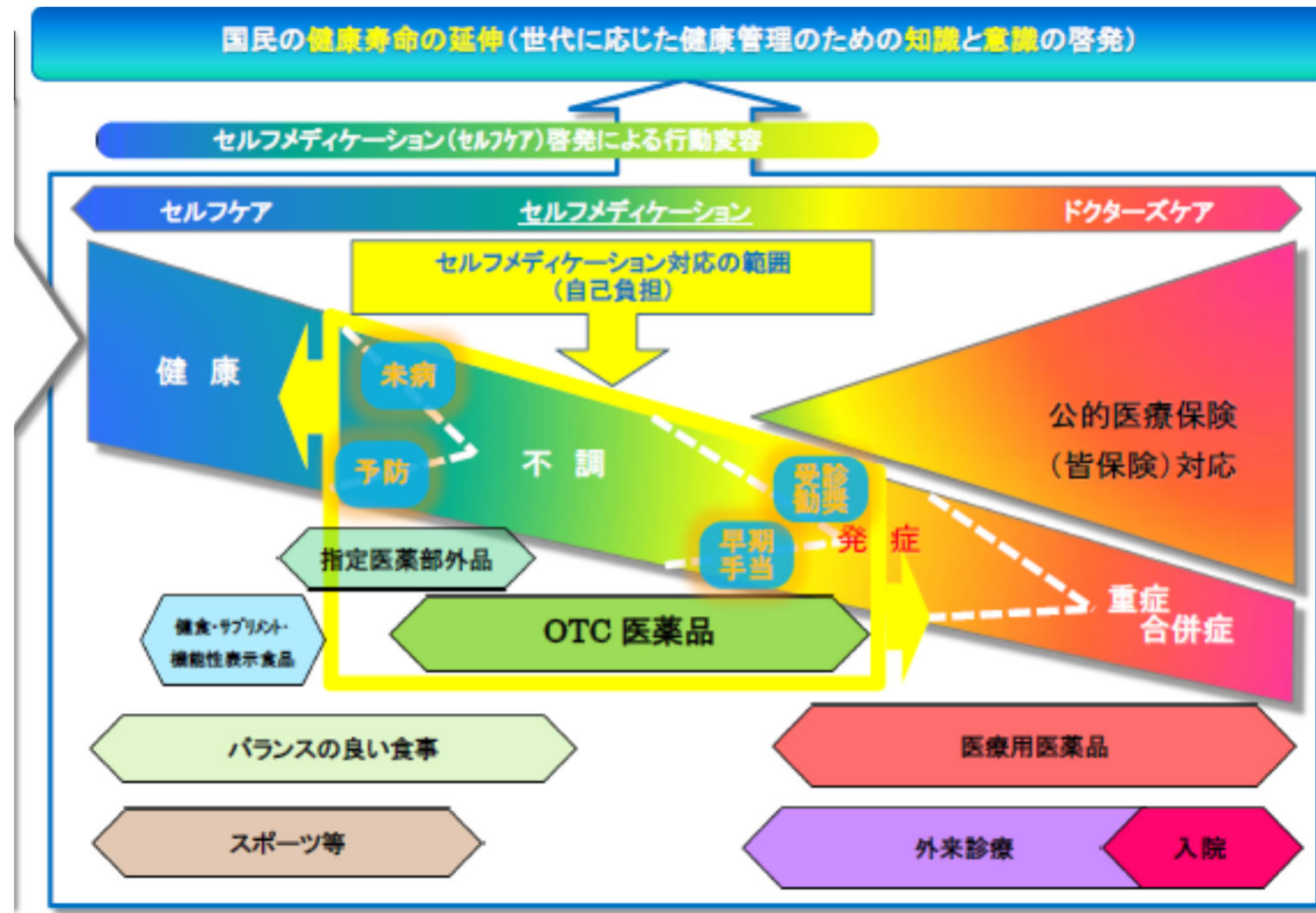


Increased medical expenses
could rise over 400 billion
US\$ soon.





Self-Medication could contribute to solve the health issues (Grand Design for OTC Industry by2025)





Vision for OTC Industry (3 Principles in 2025)



- Self-Medication and Self-Care contribute the nation for its Healthy Active Longevities
- “Community Health Station” works well for the implementation of Self-Medication and Self-Care
- In ASEAN and other countries, the Japan-model is utilized for the Healthy Active Longevities

Recently approved Ingredients in the Pharmacist Intervention Required Medicines (*Switched OTC or Direct OTC*) in Japan

<i>Year</i>	<i>Ingredient</i>
2010	Epinastine Hydrochloride ; Becrometazone propionate (<i>nasal spray</i>)
2011	Clotrimazole * ; Mixture of dried-extract of red vine leaf (<i>Flaven TM</i>) ; Oxymethazoline hydrochloride (<i>nasal spray</i>) ; Acitazanolast hydrate (<i>eye drops</i>) ; Mequitazine < <i>new dosage</i> > ; Ibuprofen + Scopolamine butylbromide ; Pemirolast pottasium
2012	Neticonazole hydrochloride ; Ibuprofen < <i>new dosage</i> > ; Fexofenadine hydrochloride ; Pemirolast potassium * ; Ketotifen fumarate + Naphazoline hydrochloride (<i>nasal spray</i>) ; Cetirizine hydrochloride ; Ethyl icosapentate
2013	Pemirolast pottasium ; Evastine ; Tranilast ; Trimebutine maleate
2014	Chasteberry extract ; Alminoprofen