

Assessing unproven practices: Japan's example

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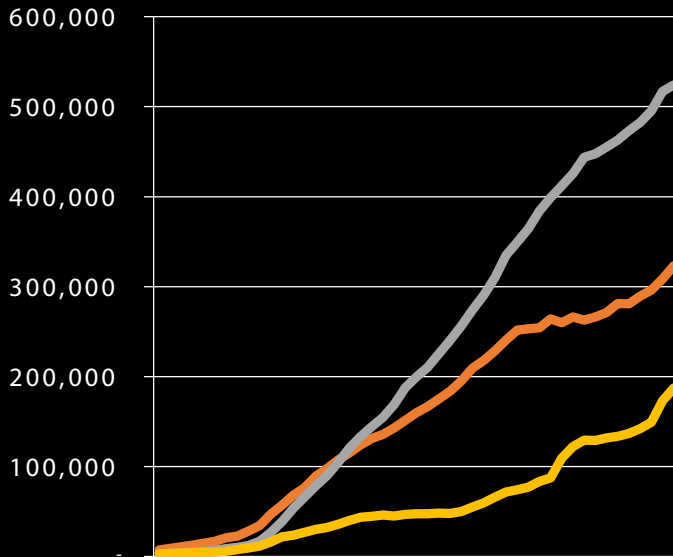
Director, Cochrane Japan

National Center for Child Health and Development

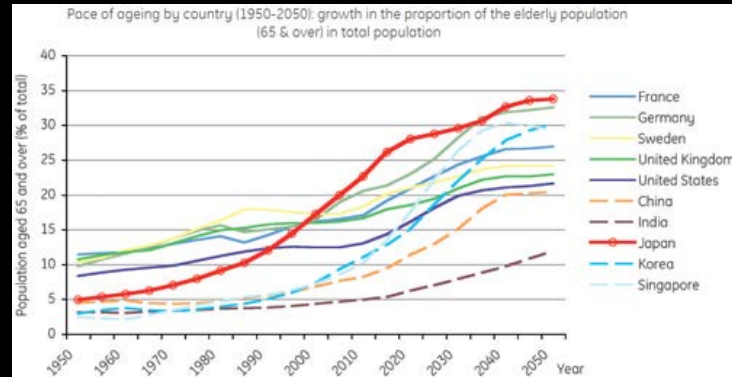
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The most ageing country in the world!

Social security (1964-2010)



Ageing



Assessing unproven practices

Approval by PMDA

Pricing in national health insurance

Practice regulations by
clinical practice guidelines
driven by professional organizations

Assessing technologies for approval

PMDA and others

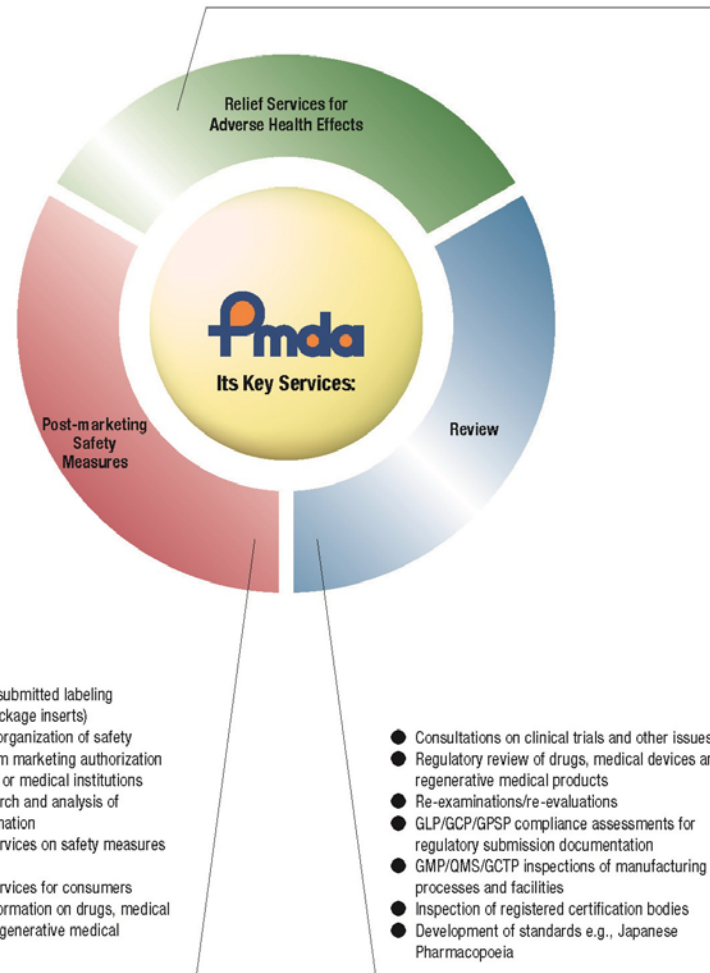
Services of PMDA

PMDA

PMDA (Pharmaceuticals and Medical Devices Agency) is Japanese regulatory agency, working together with Ministry of Health, Labour and Welfare.

“We conduct scientific reviews of marketing authorization application of pharmaceuticals and medical devices, monitoring of their post-marketing safety. We are also responsible for providing relief compensation for sufferers from adverse drug reaction and infections by pharmaceuticals or biological products.”

- Relief service for adverse drug reactions
- Relief service for infections acquired through biological products
- Health allowances etc., for SMON patients
- Health allowances for HIV-positive and AIDS patients
- Financial assistance under the “Act on Special Measures concerning the Payment of Benefits to Assist Individuals Affected by Hepatitis C through Specified Fibrinogen Products and Specified Blood Coagulation Factor IX Products Contaminated by Hepatitis C Virus”



PMDA review

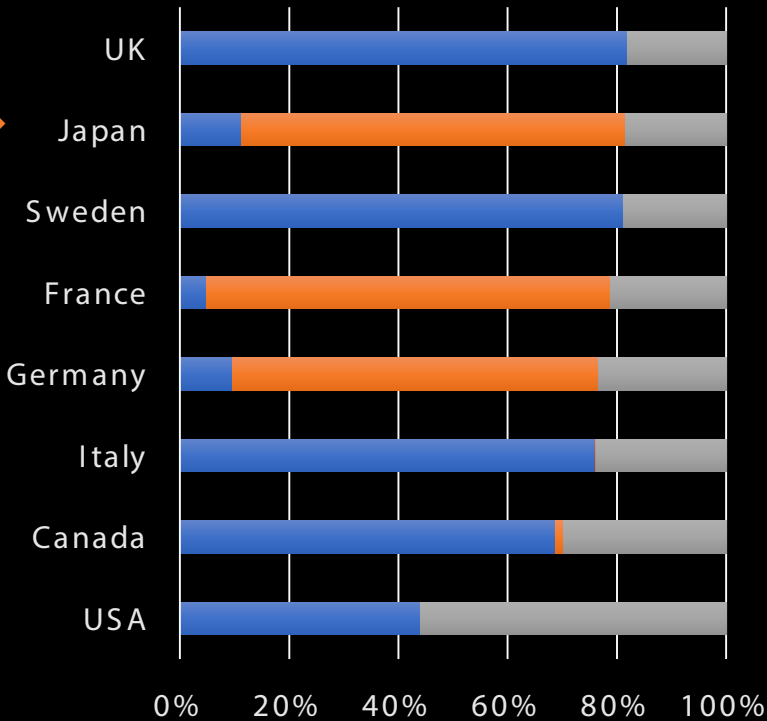
- Clinical trials and animal studies
- Focus on drug/device safety
- Collaborate with FDA and EMA
- Minimum focus on cost-effectiveness

Assessing technologies for insurance

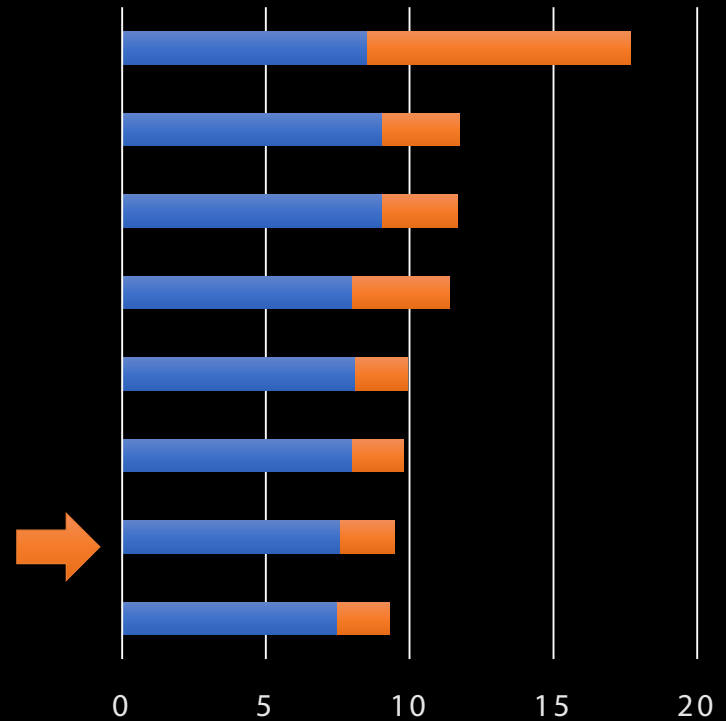
Central Social Insurance Medical Council (Cho-I-Kyo), run by
the Ministry of Health, Labour and Welfare

Health expenditure – public private ratio

Proportion of public expenditure in all health expenditure



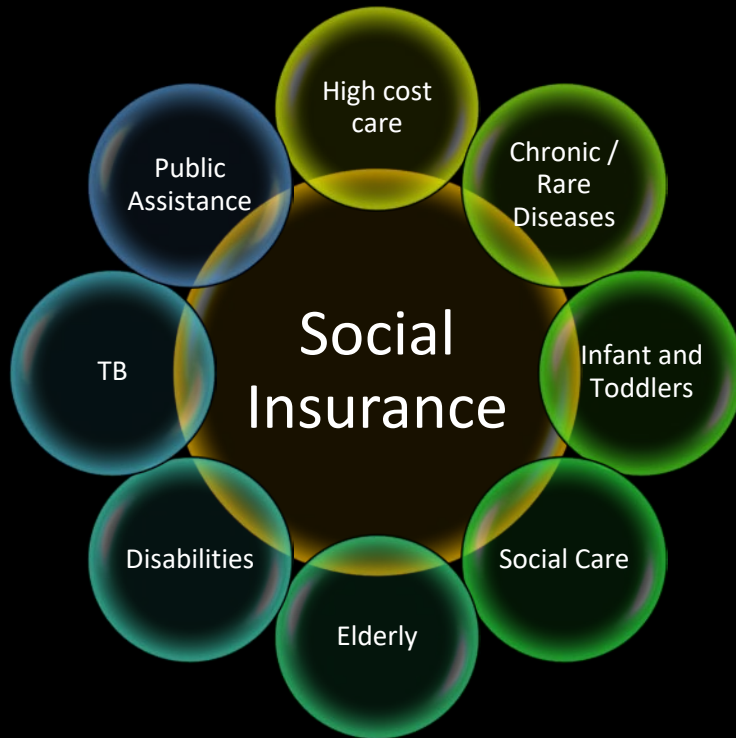
Proportion of health expenditure in gross national product



Mainly by social health insurance, strongly public oriented financing system

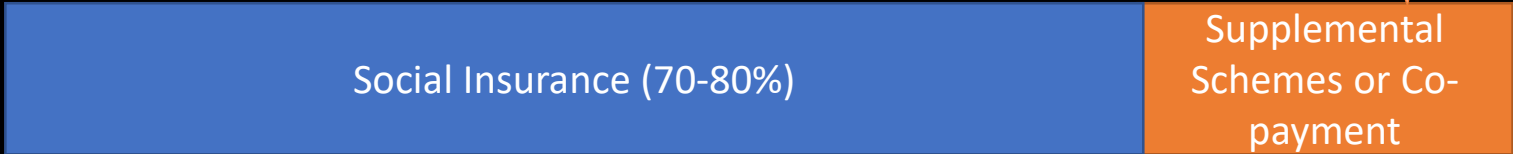
Financing Clinical Care in Japan

Hybrid between insurance and tax



Adult patients of families with relatively affluent income and with acute and mild conditions pay the “co-payments”.

Healthcare cost paid by



Virtually no “private” hospital

National Social Health Insurance Scheme
(prohibiting mixed payments)

University
Hospitals

Governmental
Hospitals

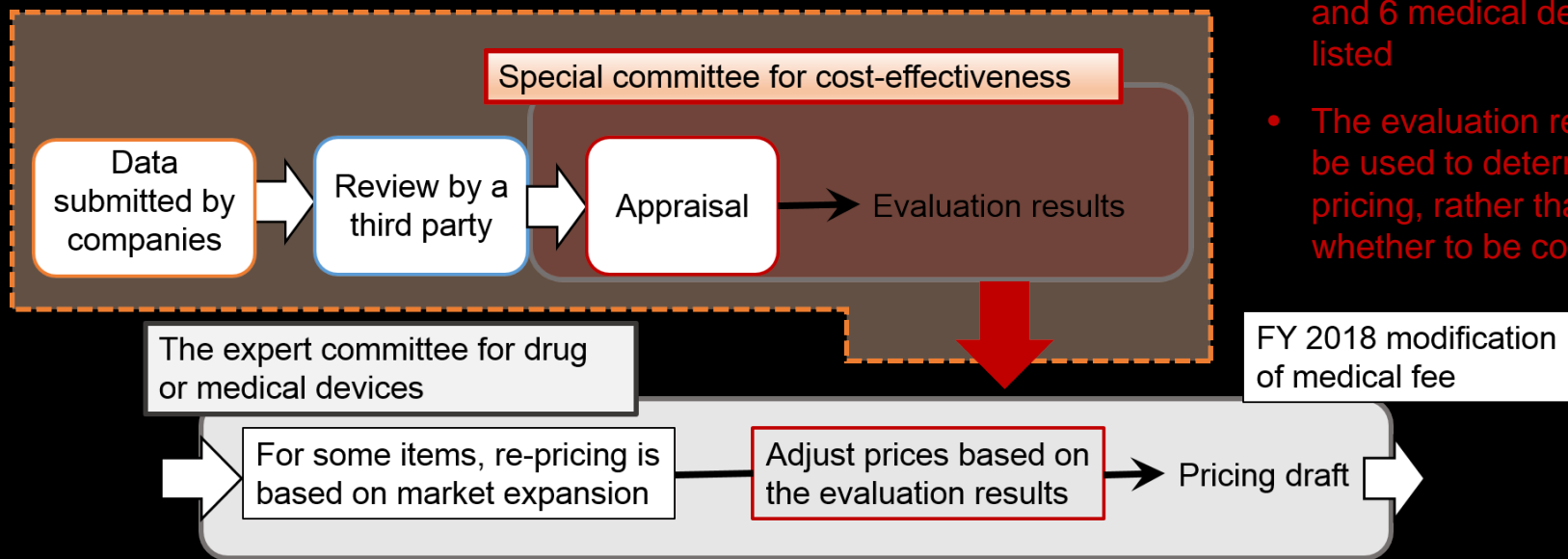
Other
Hospitals
including
those run
privately

Clinics

Central Council of Social Medical Insurance

- Role: revise the fee schedule every two years
- Members:
 - service providers: doctor, dentist, pharmacist, hospital
 - insurers: insurer union, employer, labor union
 - public interests: academia, cancer society
- Sub-committees:
 - Costing / Drug price / Health technology assessment

A pilot introduction of cost-effectiveness evaluation of drugs and medical devices since April 2016



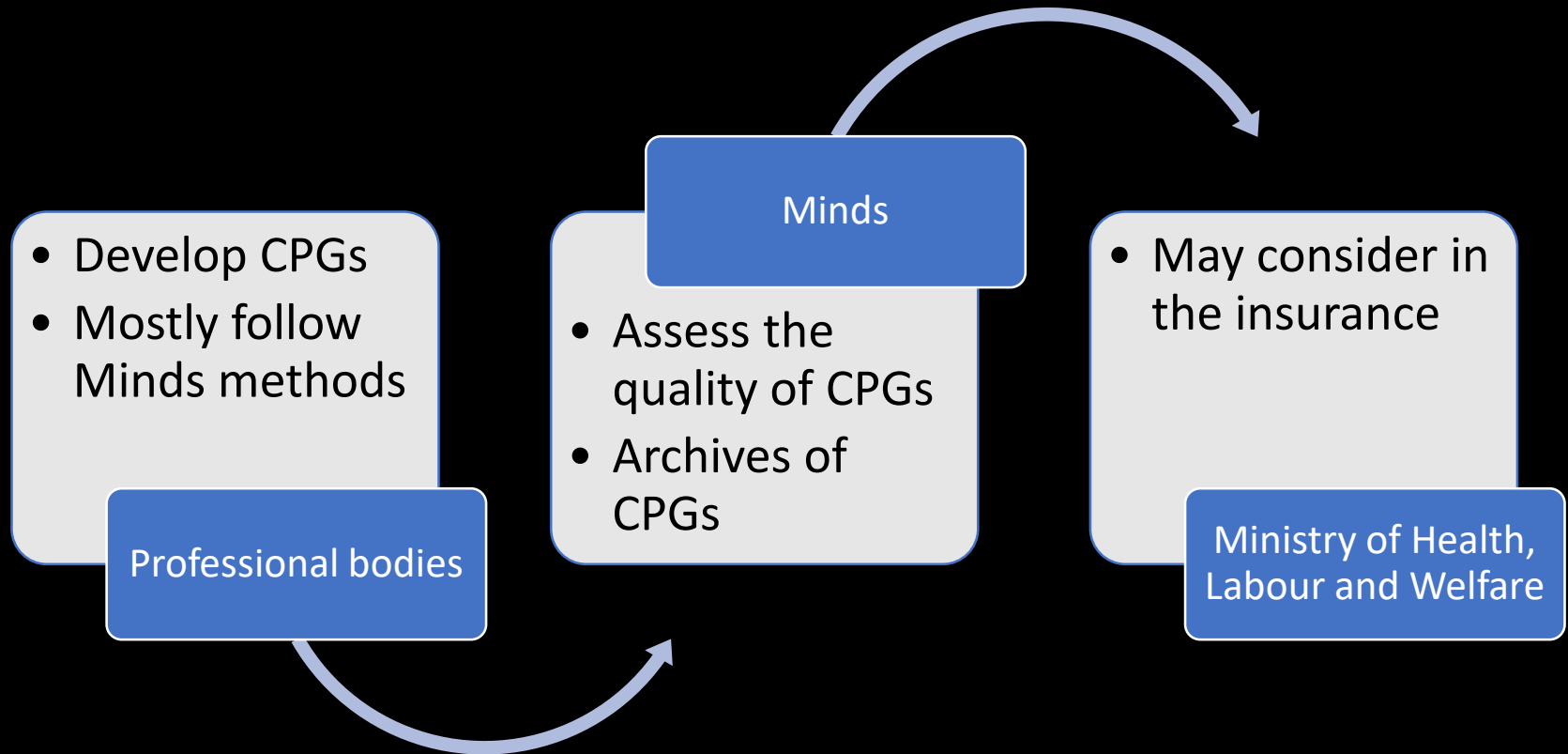
- Target products: 7 drugs and 6 medical devices listed
- The evaluation results will be used to determine re-pricing, rather than whether to be covered

Assessing technologies by professional bodies

Clinical practice guidelines

Minds

*Guideline agency funded by the Government,
hosted by Japan Council for Quality Health Care*



Minds

Japanese



Medical Information Network Distribution Service
financially supported by Ministry of Health, Labor and Welfare of Japan as a consignment project

HOME » English

Guidelines

Reports

User Guide

Developer Guide

About Minds

Publication Criteria for the English Version of Clinical Practice Guidelines (CPG) in MINDS

MINDS has been publishing CPG in English according to the following criteria:

1. The original Japanese CPG has already been published on the MINDS website.
2. The English version of Japanese CPG has been produced by the guideline development group.
3. The publication consent for the English version has been obtained from the authors.
4. The English version was approved for publication by the CPG evaluation committee in MINDS.

See Also: [Procedures for the Evaluation, Selection and Publication of Japanese Clinical Practice Guidelines \(CPG\) in MINDS](#)

- [All\(28\)](#)
- [Neoplasm\(8\)](#)
- [Central nervous system\(5\)](#)
- [Musculoskeletal system\(2\)](#)
- [Cardiovascular system\(3\)](#)
- [Respiratory organs\(1\)](#)
- [Digestive organs\(7\)](#)
- [Oral health\(1\)](#)
- [Kidney and urinary tract\(6\)](#)
- [Allergy and collagen disease](#)
- [Skin, eyes, ear, nose and throat\(3\)](#)
- [Women's health, pregnancy and childbirth\(4\)](#)
- [Pediatrics\(5\)](#)
- [Mental health](#)
- [Infection\(2\)](#)
- [Health examination and prevention](#)
- [Emergency care\(2\)](#)

Empowering general public

- Minds
- Cochrane Japan
- Testing Treatments
- NGOs such as COML

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