Risk Sharing Agreements for Health Technology Assessment Experience in Taiwan

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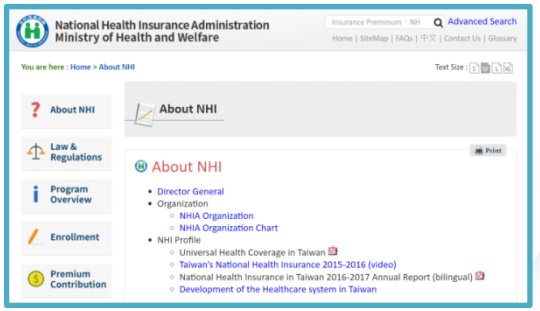
1. HEALTHCARE SYSTEM AND NATIONAL HTA BODY

About Taiwan

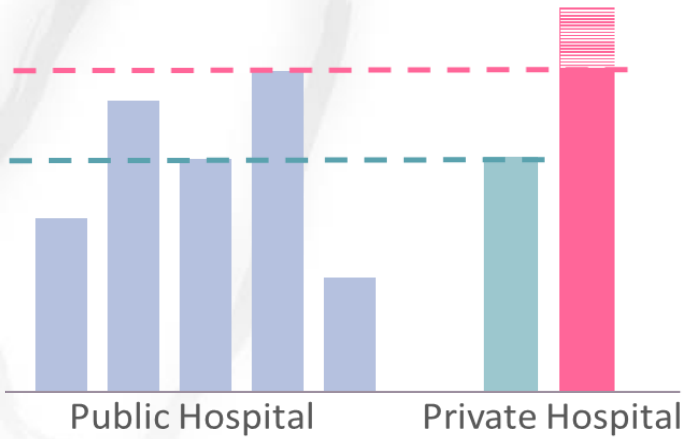
- **Population**
  - 23.5 million (Dec 2016)
  - Aging society (ageing index: 98.86 (Dec 2016))
  - Expected life years at birth: 80.2 years (77.0 years for men and 83.6 years for women in 2015)
- **2015 GDP per capita (nominal) - US$ 22,384**

Health Care

- **Current Health Expenditure as % of GDP – 5.9 %** (2014)
- **National Health Insurance**
  - Introduced 1995
  - Mandatory, single-payer social health insurance
  - Comprehensive
  - Low premium & low co-payment



Different hospitals in the public sector charge various prices for the same drug.



1995. 09
Drug Benefit Committee

2008. 01
HTA is introduced by DOH policy

2013. 01
Expert Meeting & PBRS Joint Committee

1950~1994

GESSI & Labor Insurance

Adopt the prices claimed by **Public Hospitals**

1995~2012

First-Generation NHI

Unified Drug Price System Set up by BNHI since 1996

2013~

2nd-Generation NHI

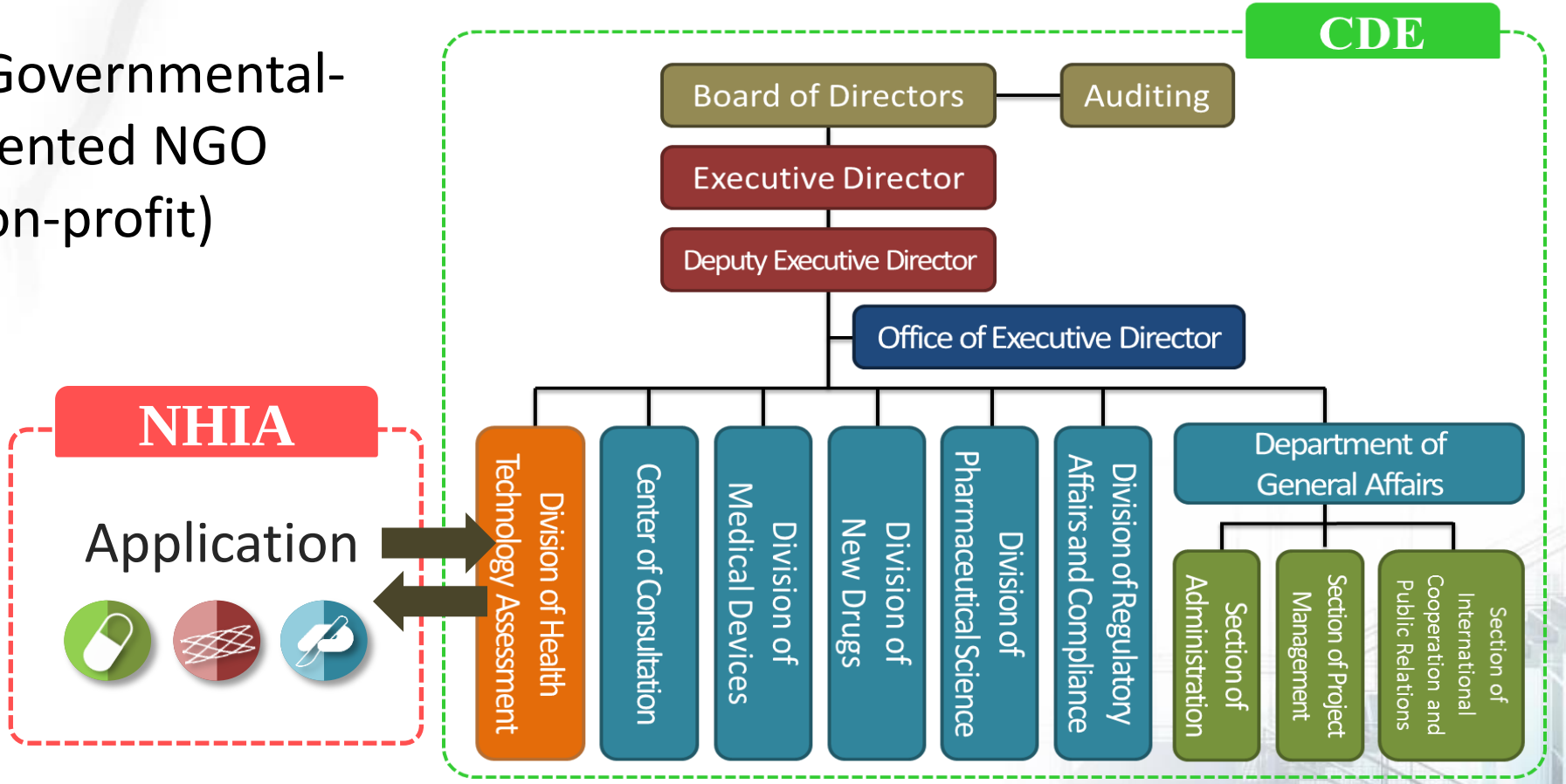
Pharmaceutical Benefit Scheme

BNHI renamed as NHIA since July 23, 2013

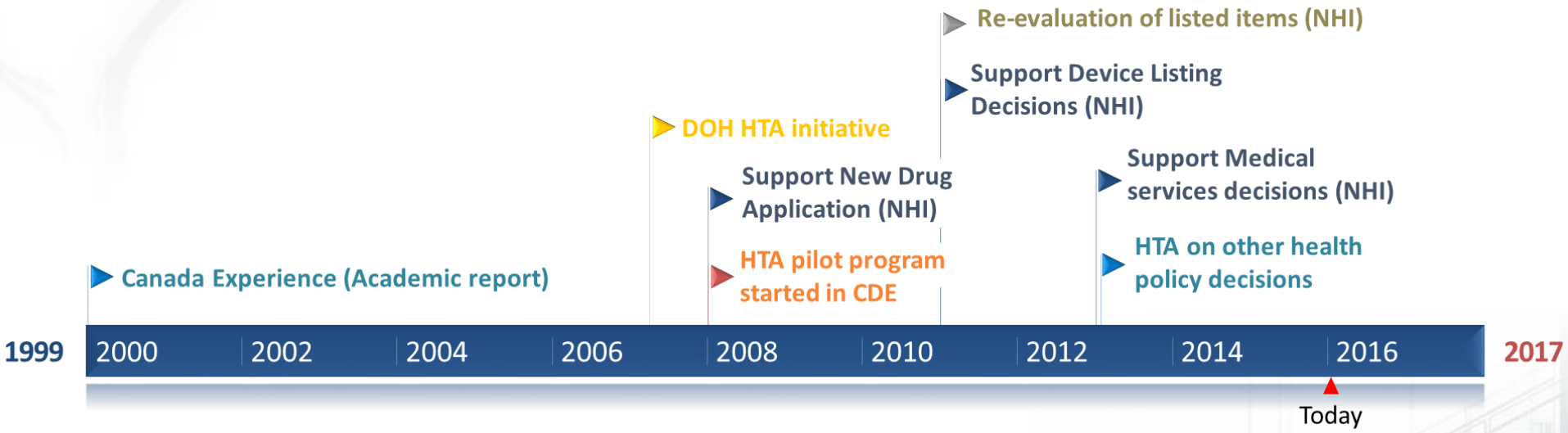
GESSI: Government Employees' and School Staffs' Insurance
PBRS: Pharmaceutical Benefit and Reimbursement Standard
BNHI: Bureau of National Health Insurance
NHIA: National Health Insurance Administration

The organization of HTA function

A Governmental-oriented NGO (non-profit)

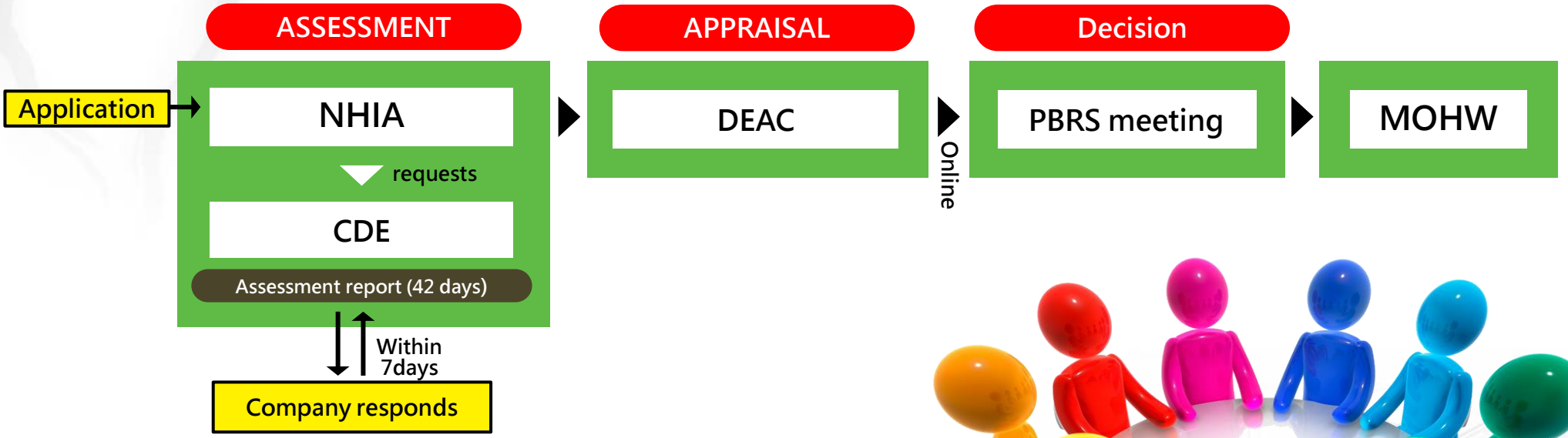


Historical development of HTA in Taiwan



2. THE ROLE OF HTA IN SUPPORTING BENEFIT PACKAGE

Current Process of New Drug Application



NHIA: National Health Insurance Administration (former: BNHI)
DEAC: Drug Expert Advisory Committee
PBRS: Pharmaceutical Benefit and Reimbursement Standard
MOHW: Ministry of Health and Welfare

Assessments reports produced

Assessment working process

HTA report

- **Structured and formal**

Basic info of the application		
Executive summary	• Recommended comparator • Ethical issues • Budget impact • Reimbursement criteria recommendations from NICE, PBAC, or CADTH	• Relative effectiveness • Cost-effectiveness • Comparison table
Report	1.Disease and treatment options	
	2.Other listed medications (to the target populations)	
	3.Evidences of clinical effectiveness	• Considered evidences by CADTH, PBAC, NICE • Cochrane/PubMed/Embase search • Others
	4.Summary of clinical effectiveness	
	5.Evidences of cost-effectiveness	• Local PE • Considered evidences by CADTH, PBAC, NICE • Cochrane/PubMed/Embase search • Other CEA literatures
	6.Evidences of disease burden and financial impact	• Disease burden • Comparator recommendations • BIA estimates
	7.Summary of economic considerations	
References		
Appendix		

Guidance of Conducting BIA

Structure

1. Target population: Match with the recommended (by company) indications
2. Perspective: Budget holder (NHIA)
3. Budget boundaries (The extents of the costs included in the analysis)
4. Time horizon: 5 years
5. No need for considering discount and inflation
6. Analytic framework: clear and simple whenever possible
7. Place of therapy and relationship with listed treatments: replace or addition

Analysis

8. Estimation of eligible patient populations
9. Market share for the next 5 years
10. Unit costs
11. Total costs and budget impact
12. Parameters and assumptions
13. Sensitivity analyses

Vali-dation

14. Model validation
15. Model transparency: properly use computer software

Budget Impact Analysis

- Financial impact estimation

Year of reimbursement	1	2	3	4	5
Melanoma pt's	367	383	402	421	441
% of **inoperable or metastatic**	28.3%				
Gene X mutation %	25.5%				
Market share	65%	70%	75%	80%	80%
# of patient use	17	19	22	24	25
Annual expenses (1000 NTD)	30,600	34,200	39,600	43,200	45,000

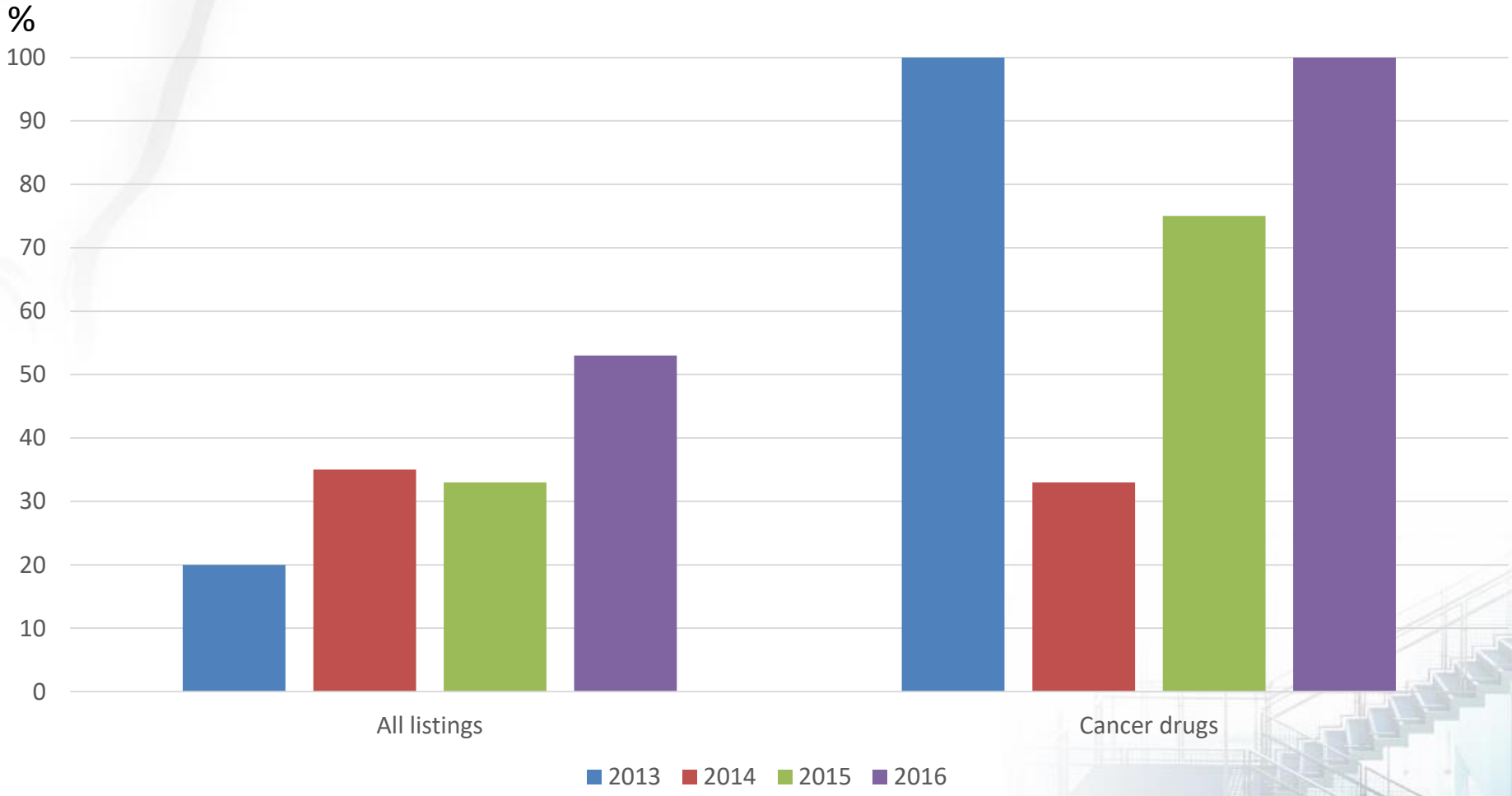
Risk Sharing – mostly PVA

- Mostly in price-volume-agreement form
- Rules:
  - New Drug: Any one of the initial 5 years (after listing) is expected to spend over 0.2 billion TWD
  - New indication: 0.1 billion TWD
- Manufacturers submit the target numbers of the 5 years
  - Contracting: If the real usage exceeds the target numbers then certain amount (no more than 40% of the excess) of the exceeded amount needs to be paid back to NHI

BIA is important

- Negotiation is heavily relied on the BIA estimates
  - Too large – not likely to get reimbursed
  - Too small – possibly a lot rebate later (example: Nexavar)

Percentages of signing PVA



Source: NHIA 2018

Another type of risk sharing

- Revlimid (lenalidomide) Capsules for multiple myeloma
- NHI pays the first 10 cycles (each cycle means 21 days of a 28-day cycle), the company pays the rest

(not in effect now)

Performance-based risk sharing

- DAAs for hepatitis C treatments
- SVR12: yes – NHI pays; no – the company pays

To list or not to list?

- ✓ (comparative) effectiveness
- ✓ Cost-effectiveness
- ? Budget impact
- ✓ ELSI

Also considering:

- Public health implication in Taiwan
- Academia value

How many CHC patients?

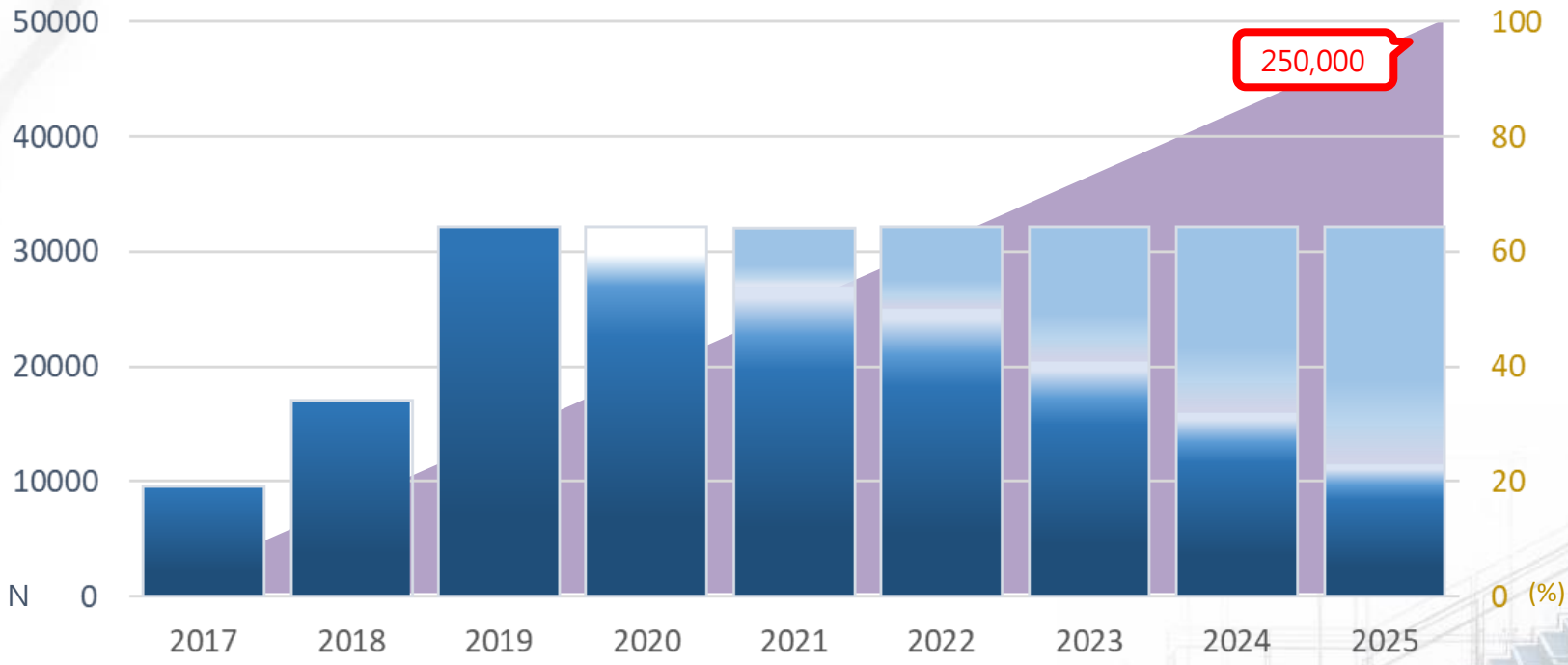
Data source	Year of patient-collection	Estimated numbers of anti-HCV(+) in Taiwan	Estimated numbers of HCV RNA (+) in Taiwan
Chen, Yang, Huang, 2007	1996-2005	423,283	275,134
Yu ML, Yeh ML, Tsai, 2015	1996-2005 (mainly)	745,109	484,321
TwHHH[a]	2002	613,189	398,573
NHCP[b]	1996-2016	633,456	411,746
Median	**--**	**623,323**	**405,160**

[a]TwHHH: Taiwanese Survey on Hypertension, Hyperglycemia, and Hyperlipidemia
[ab]NHCP: National Hepatitis C Program Office, MOHW

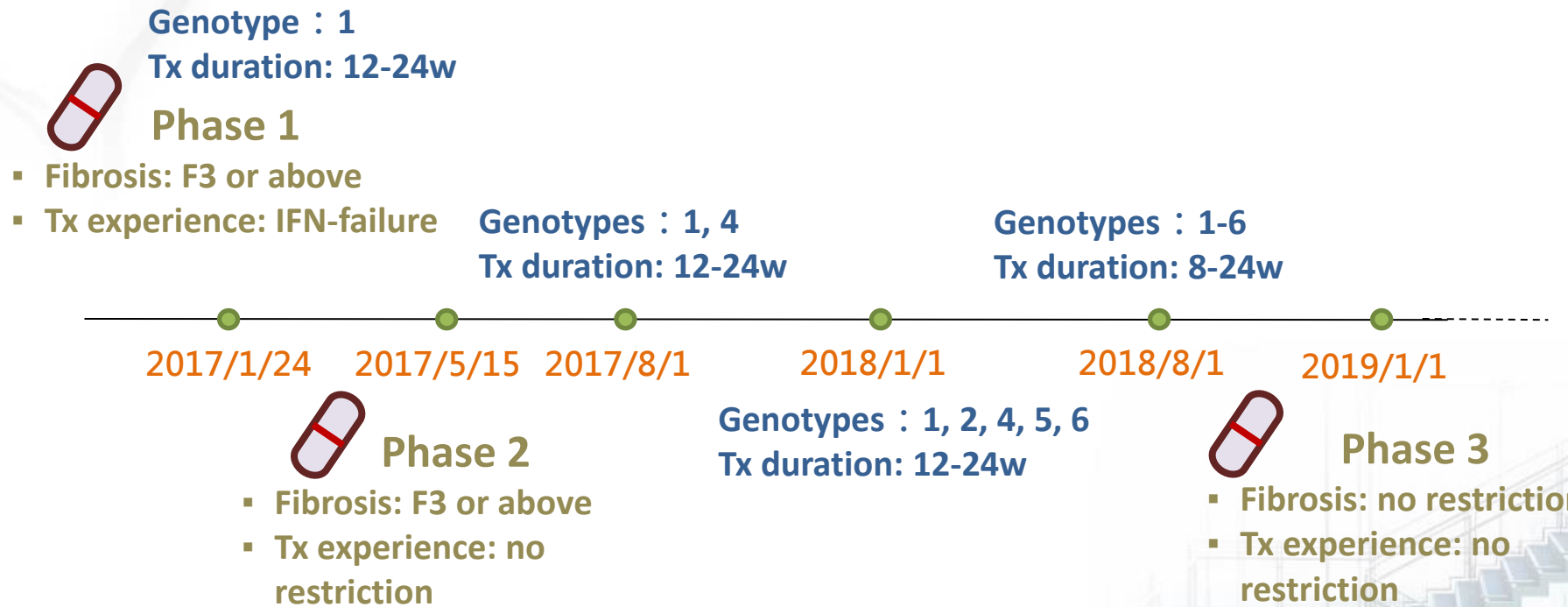
Around 6,800 new infections each year
≈ 6,000 expired patients

How to find the patients?

- Clinical setting (NHI) and screening from the community

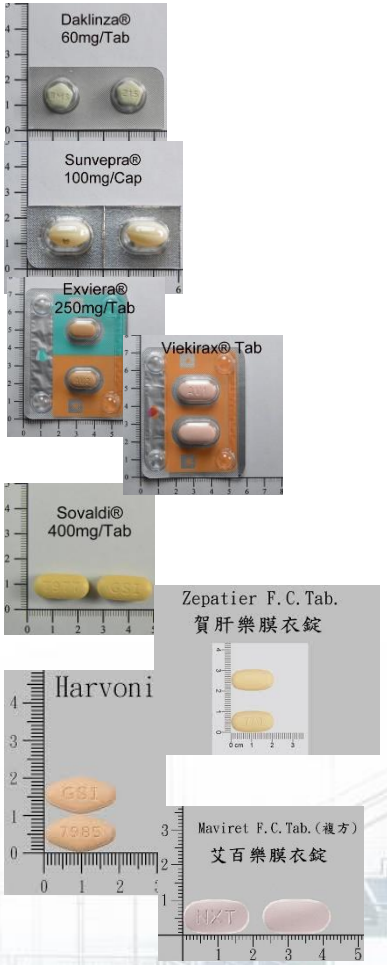


DAAs NHI listing



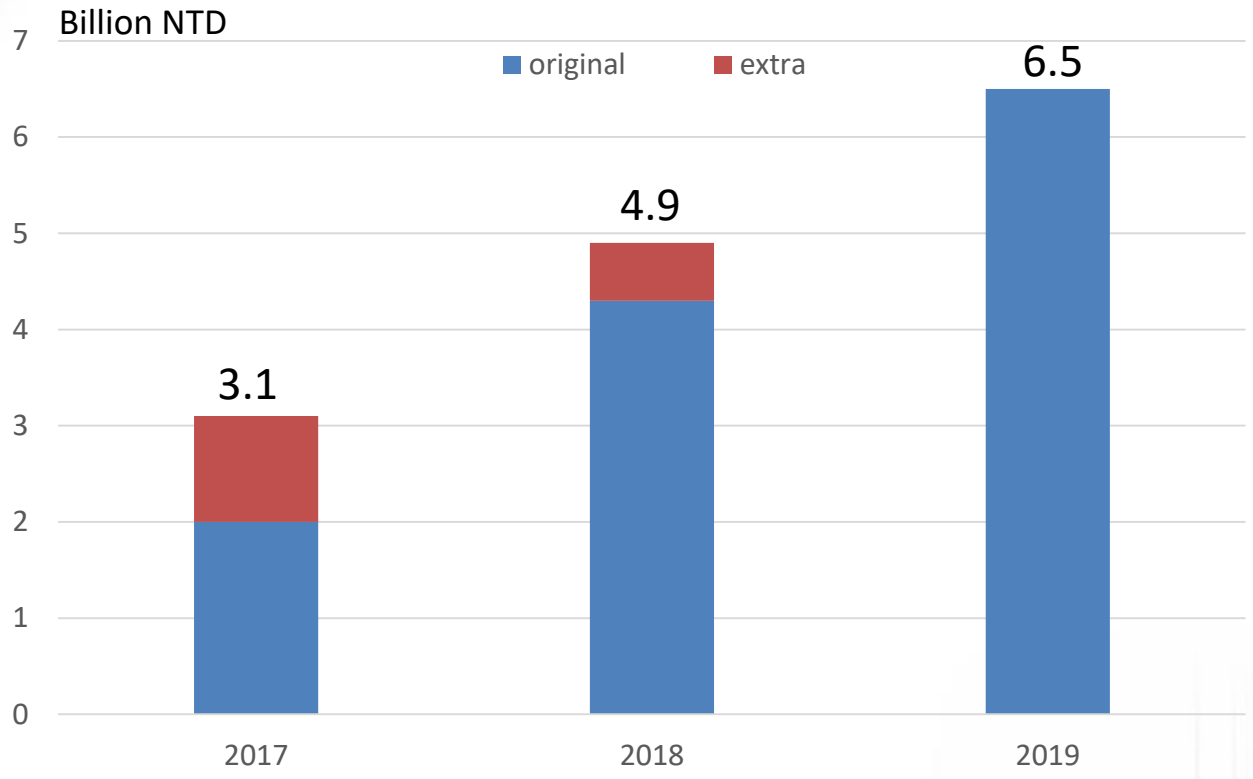
Current DAAs listed

Brand name	Genotypes	Dosage	Course (weeks)
Daklinza	1b	1# QD	24
Sunvepra	1b	1# BID	
Exviera	1a, 1b	1# BID	12
Viekirax	1a, 1b	2# QD	
Sovaldi	2	1# QD	12
Zepatier	1a, 1b, 4	1# QD	12/16
Harvoni	1, 2, 4, 5, 6	1# QD	12
Maviret	1, 2, 3, 4, 5, 6	3# QD	8/12/16
Epclusa	1, 2, 3, 4, 5, 6	1# QD	12



藥品圖片來源：
http://www.kmtth.org.tw/med/index.asp
https://www.paochien.com.tw/pharmacy/drugquery

Allocated budgets for DAAs

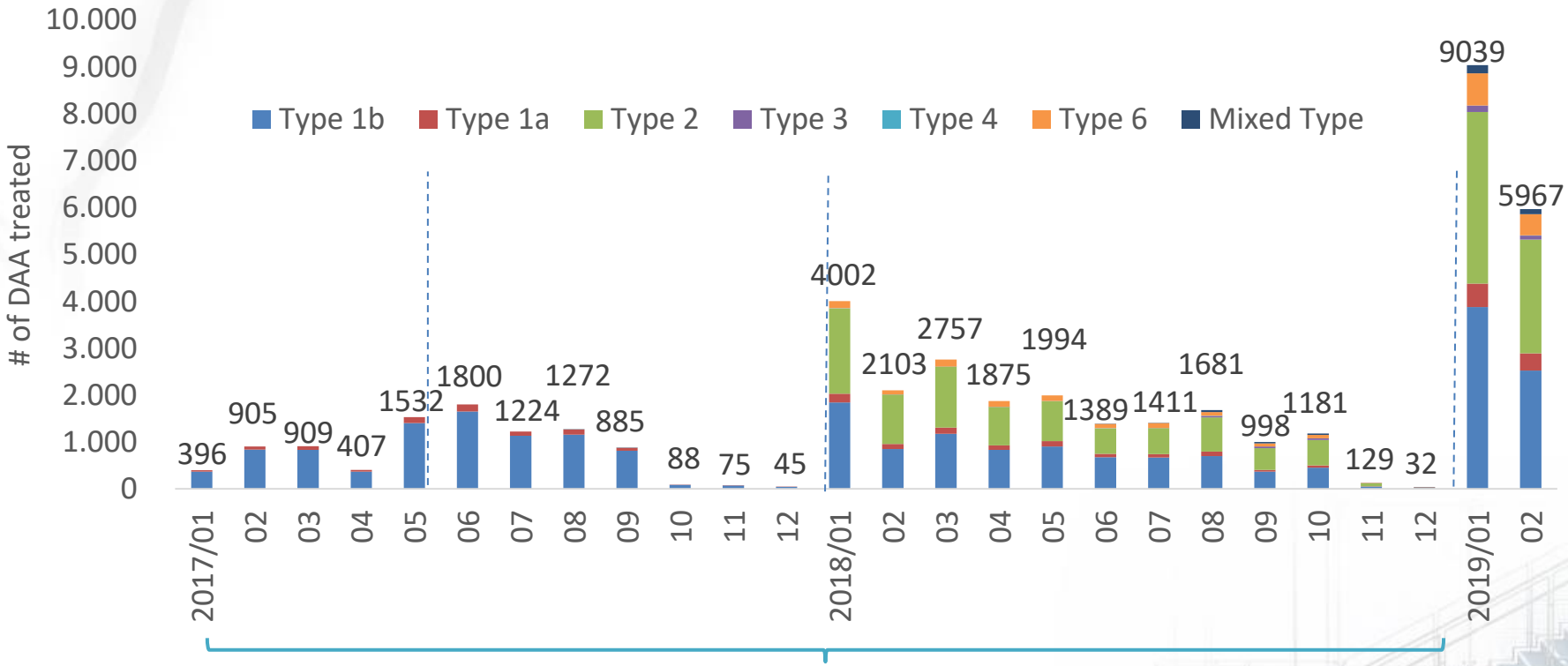


No of patients	8000 (9538)	20000 (19549)	40000

DAA-treated CHC patient registry

Week 0, 4, end of treatment, 12wks after tx

Number and genotypes



SVR (completed course) : 97.0%

(Data till 2019/2/27)

“MEA” for high cost-oncology drugs

- For high-cost oncology drugs (estimated amount of reimbursed drugs at any one year > 500 million TWD), NHIA has announced so-called 'MEA' rules. There are 6 types of arrangements that the applying company can choose. (Since 2018)
  - Not detailed enough (local CEA reports in 2 years?)
  - Still under development

immunotherapies

- 3 PD-L1 inhibitors (nivolumab, pembrolizumab, atezolizumab) reimbursed on all TFDA-approved indications, including 8 types of cancers (i.e, liver cancer) (since April 1, 2019)
  - A total of 0.8 billion NTD
  - 800 patients in total
  - Need to register first (but not necessary an outcome 'registry')
  - Other requirements for industry - not very clear

Summary

- PVA is the most frequently used Risk Sharing form for NHI
  - Limitations: legal, budget-binding, etc
- Performance-based negotiation is tested well in the DAAs exercise
  - Registry
  - Requires frequent and consistent monitoring
  - not applicable to every case