

Policy for Self-sufficiency of Plasma-derived Products in Taiwan

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President

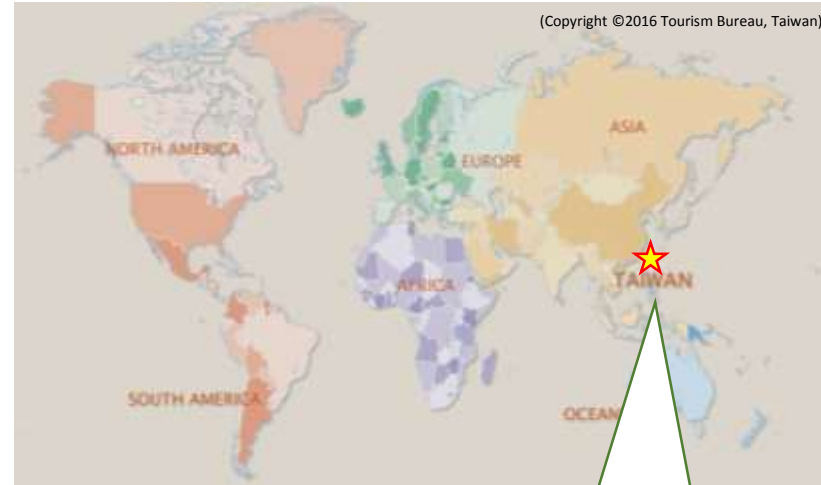
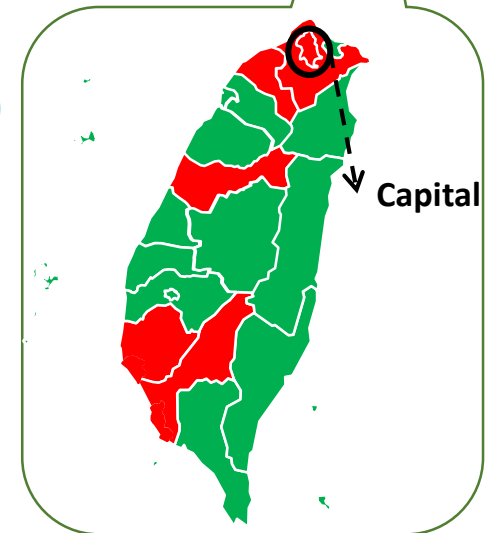
Taiwan Blood Services Foundation

Outline

- Taiwan and Taiwan Blood Services Foundation (TBSF)
- Donor recruitment and management
- Recovered plasma
- Quality and safety of plasma
- Plasma contract fractionation
- Optimize the use of IVIg and Albumin
- Prospects of plasma fractionation

Taiwan at A Glance

- Area: 36,000 km²
- Population: 23 million
- Capital: Taipei city
- GDP per capita: 22,355 USD (2015)
- 6 Metro Cities, 15 cities/counties
- Life Expectancy:
 - 80.2 years old (2015)
 - Male 77.0 years
 - Female 83.6 years
- Infant mortality: 2.5 per 1,000 (2015)
- Maternal mortality: 11.7 per 100,000 (2015)



**Ministry of Health and Welfare
(MOHW)**

**National Blood Policy
Advisory Committee
2005**

**Department of
Medical Affairs
Taiwan FDA
Taiwan CDC**

**The Blood Derivative Act
Criteria for Blood Donor Selection
2005**

Hospitals

**Taiwan Blood
Services
Foundation
(TBSF)**

Clinics

Taiwan Blood Services Foundation



5 Blood Centers

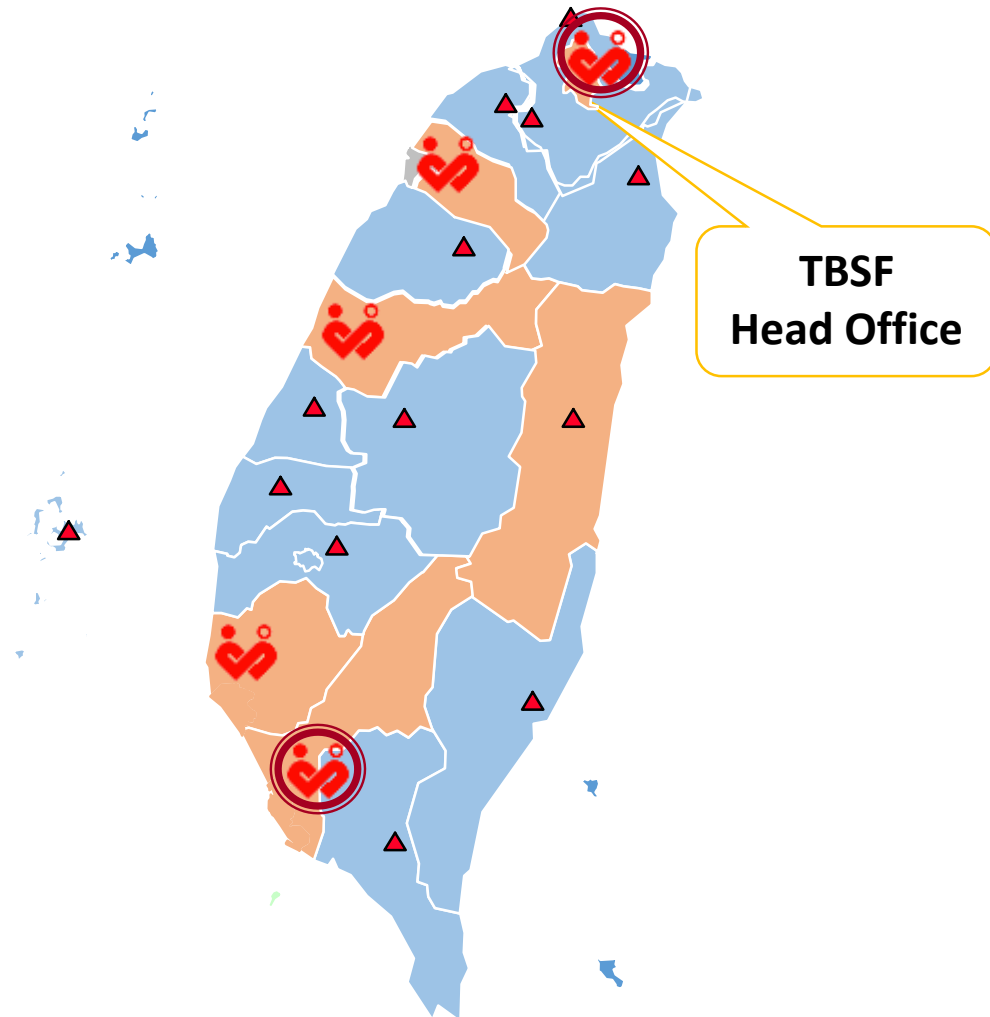


13 Blood Stations



2 Laboratory Centers

61 Fixed Blood Collection Sites





Some Policy Concerns of Plasma Derived Products

- Sufficient recovered and/or source plasma
- Safe and quality plasma

PIC/S GMP

NAT screening

- Meet the patients needs by Domestic Plasma
- Fractionation and Affordable costs

<i>Year</i>	<i>Description</i>
?	Hospital-based paid donor blood bank Community-based Red Cross paid donor blood bank
1974	Taiwan Blood Donation Association established (dual system: the existing paid donor system and VNR donor system)
1974 - 1990	Social Campaign of Voluntary NR Blood Donation
1987	Paid donor prohibited Hospital-based and Red Cross paid donor blood banks closed
1995	National Health Insurance inaugurated; blood, blood components and blood products are fully reimbursed by NHI.

A Nation-wide Social Campaign in 1974-1990

Advocate Voluntary Non-remunerated Blood Donation and disclosure of the high risks of Paid Donors.

By celebrities, movie stars, singers, musician, politicians, medical society, military units, blood donation association and government (Ministry of Education, Ministry of Defense, Department of Health).



上 | 一九八四年，我發起捐血活動，邀請羅大佑（左一）、麥嘉華（左二）、
盧敏平導演支持。
下 | 我發起「做個快樂的捐血人」活動，喬梅麗花拍攝電視廣告，左二為葛福
潤，左三為盧敏平，攝於一九八四光臨社。



伸出手臂
做個快樂的捐血人



捐血是什麼？

只要你身體健康，年滿17，沒有超過45歲，
就可將你最寶貴的血，捐給那些生命是最需要血的人！

愛，從捐血開始 1995年 中華民國捐血運動



捐血救人 從我開始

中華民國捐血運動 中華紅十字會

快樂捐血 救人益己



2002年

我不認識你 但是我謝謝你



1990年

幫助人是快樂的
你就是下一位捐血人
請帶同捐血卡或相關證明文件

快樂新血



前總統李登輝先生長期支持捐血運動，為首位挽袖捐血的國家元首。

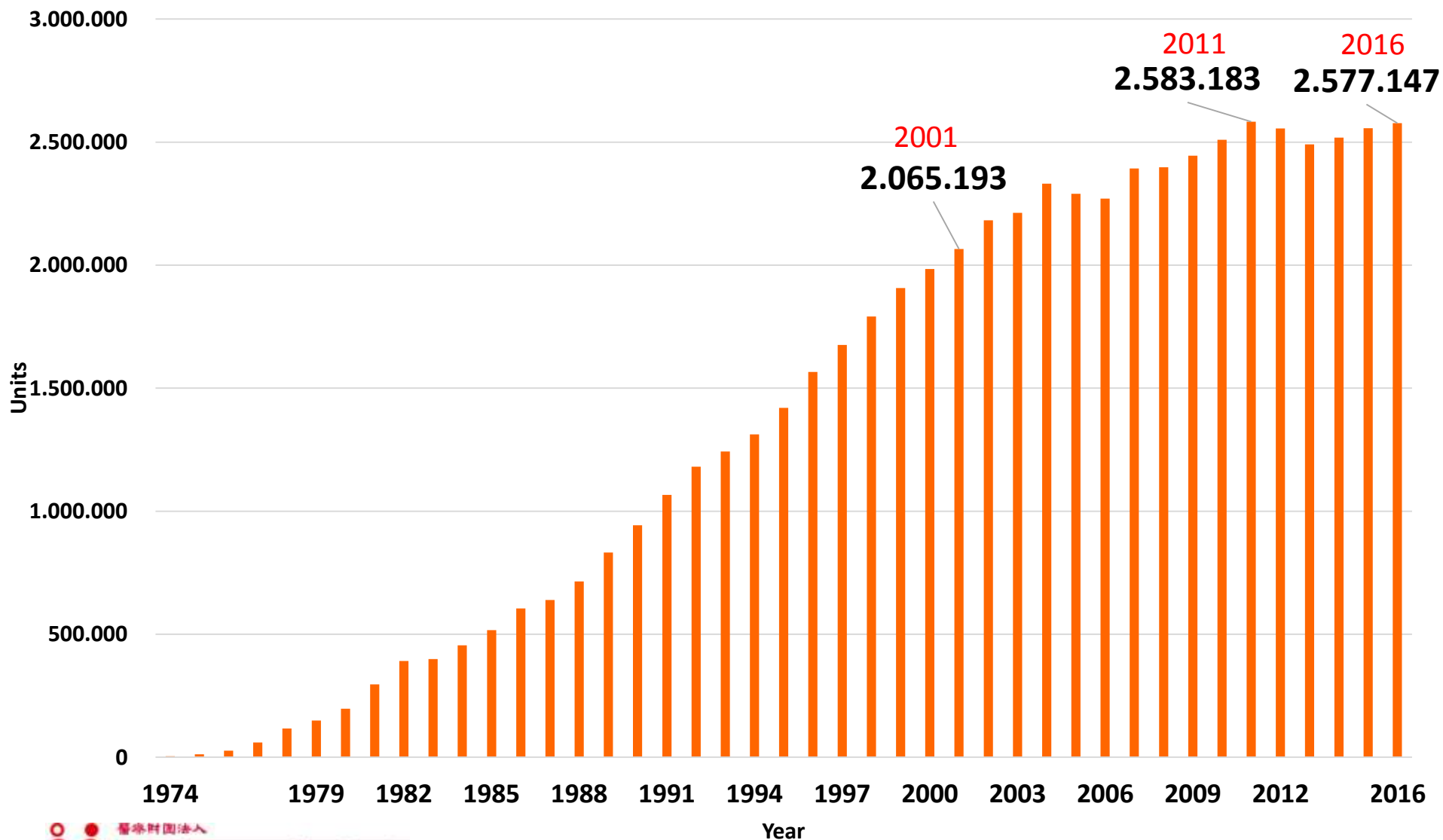


前總統陳水扁先生於91年6月6日響應臺大醫院捐血活動，完成第6次捐血紀錄。



總統馬英九先生於台北市長任內經常利用午休時間前往市府捐血室參加「分離術捐血」，目前捐血178次。

Annual Blood Collection Units, 1974-2016



- Since then, blood donation has grown along with advancement in medical care, national health insurance and reached a record high of **2,583,183 units in 2011** and **blood donation rate is as high as 8.13%.**
- In **1996** , one article of *Transfusion* recognized Taiwan's blood services as one of the fourteen advanced countries in the world with a single national blood program.

(TRANSFUSION 1996;36: 1019-1032.)

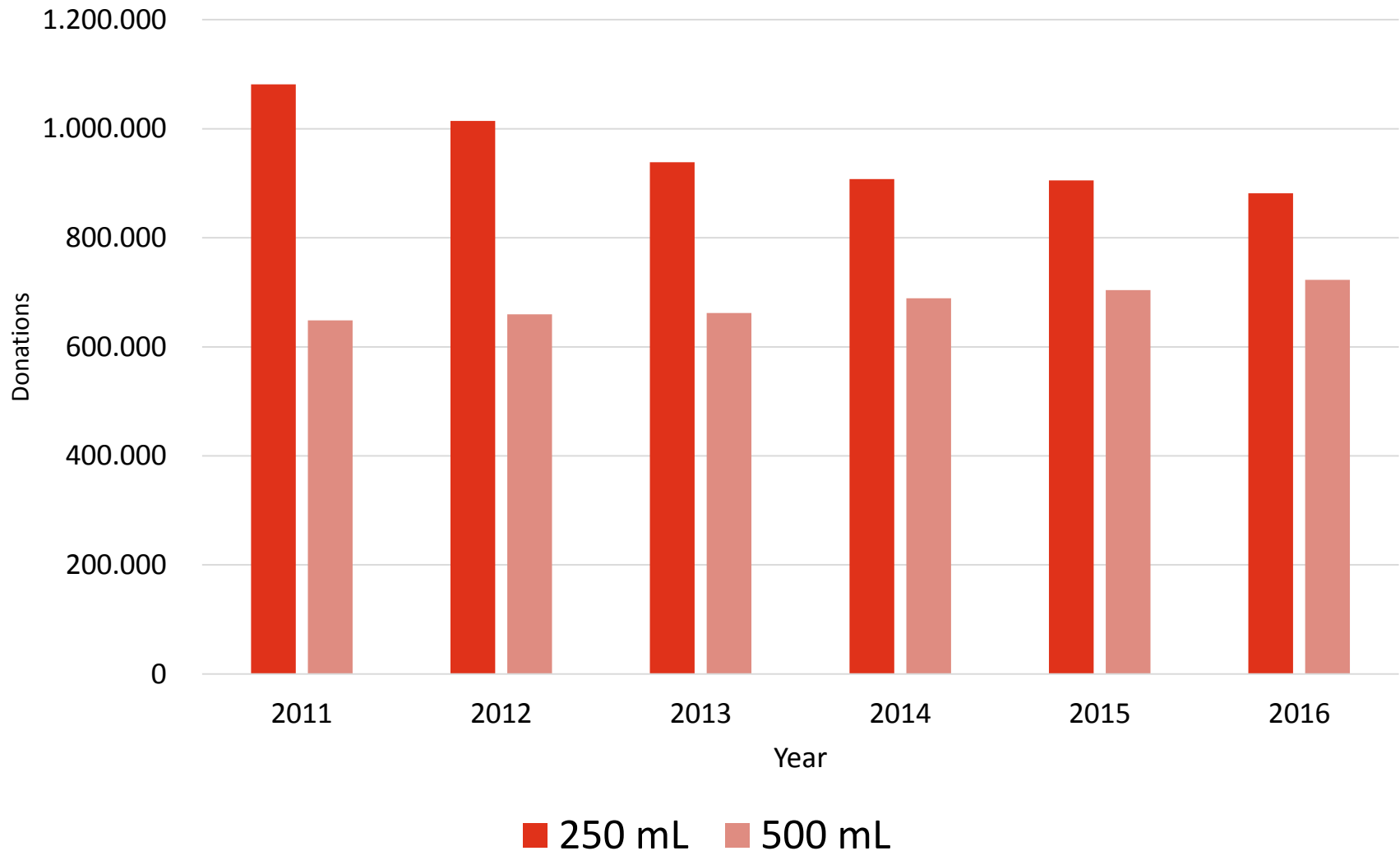
- Blood donation rate (WHO, 2012)

- High income countries 3.68%
- Middle income countries 1.17%
- Low income countries 0.39%

- Taiwan blood donation rate 7.50% (2016)

Increasing Large Volume of Whole Blood Donation

Donations of Whole Blood



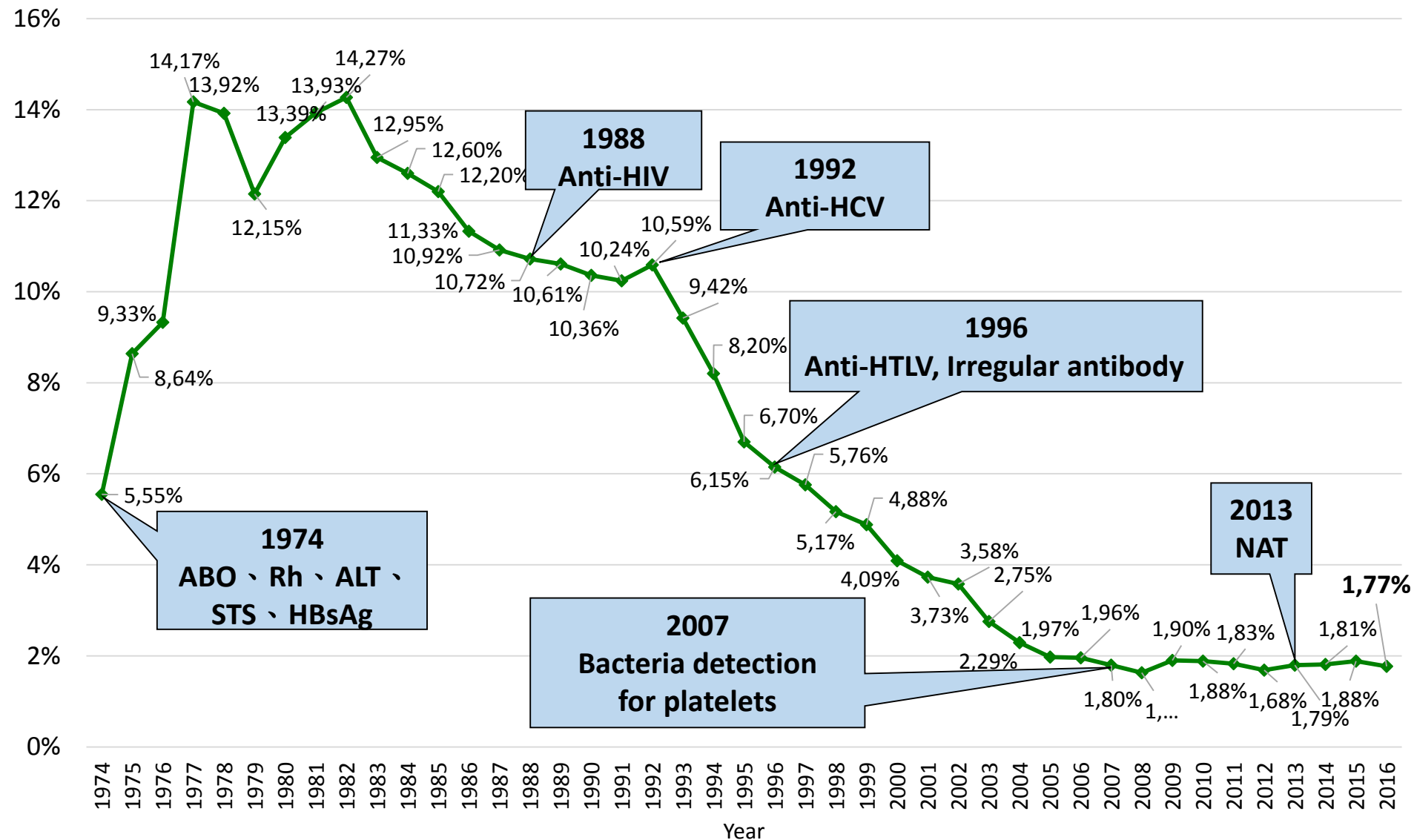
Retention of Donor - Facility and Environment



3D wall mural



The Positive Rate of Post-donation Screening Test, 1974-2016



Prevalence of TTIs among Blood Donors (2012)

Countries	HIV	HBV	HCV
High-income	0.002%	0.02%	0.02%
	0.0004-0.02%	0.008-0.24%	0.004-0.22%
Taiwan (2016)	0.003%	0.11%	0.03%
First-time donors	0.011%	1.17%	0.21%
Repeat donors	0.002%	0.02%	0.01%
Middle-income	0.12%	0.64%	0.37%
Low-income	0.85%	3.59%	1.07%

NAT for HIV, HBV and HCV

- Yield cases of

<i>Year</i>	<i>HIV</i>	<i>HBV</i>	<i>HCV</i>
2013/Feb-Dec	3	526	17
2014	1	502	8
2015	0	450	18
2016	1	396	4

- NAT for HIV Feb 2013 - 2016

- 5 ELISA(-) & NAT(+) cases in 6.9 million tests
- No transfusion-transmitted HIV infection has been reported

- A total of 27 transfusion-transmitted HIV infections during 1992 - JAN 2013

Milestones of GMP Program in Taiwan



ISO 9001
*Consolidation of
Laboratory Testing*



ISO 15189



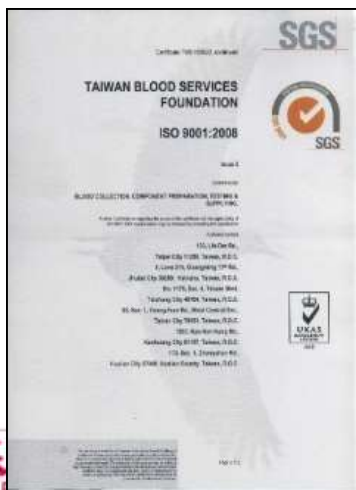
2001

2012

2014

1999

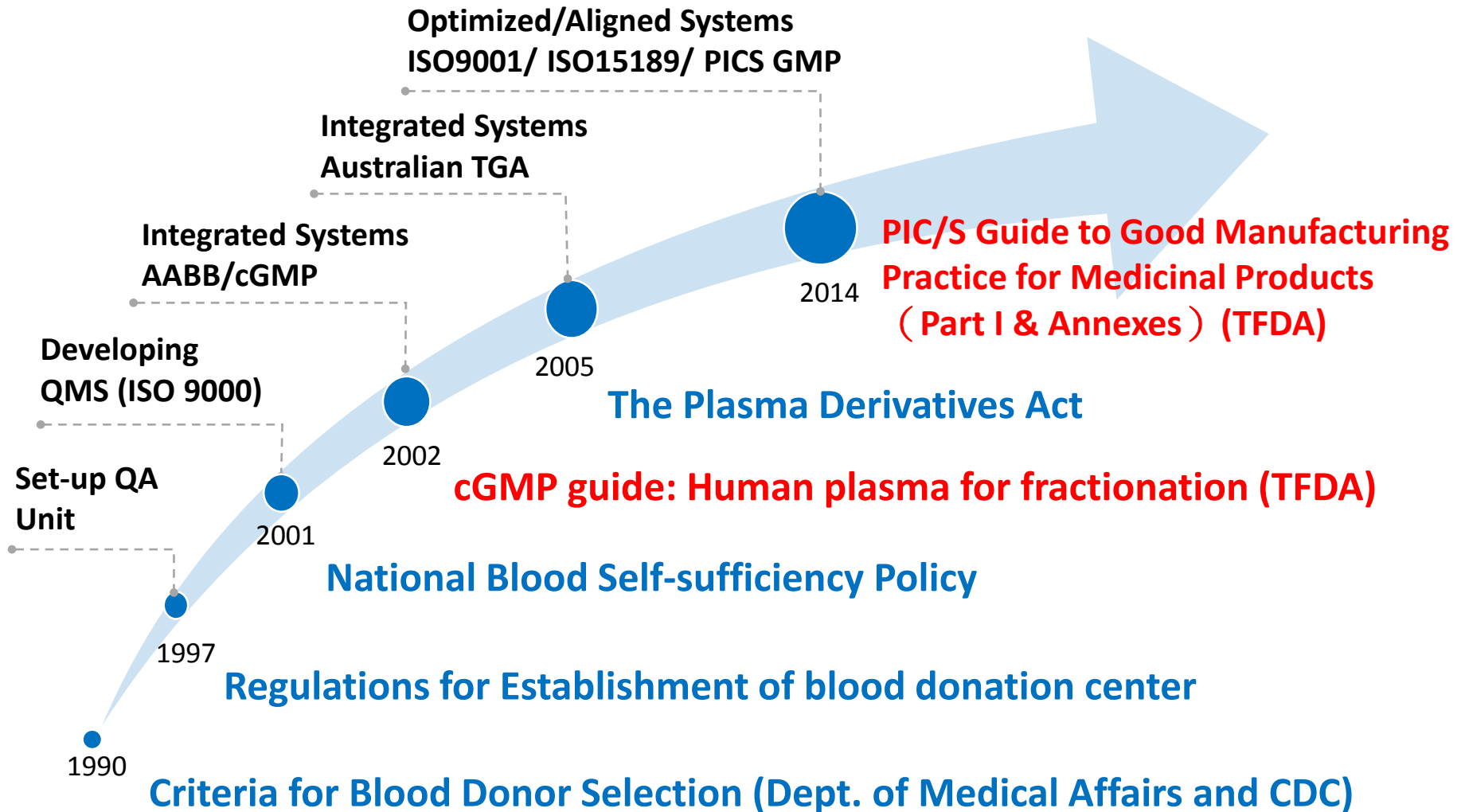
UK MCA
Initial contract
fractionation
agreement
with **SNBTS**



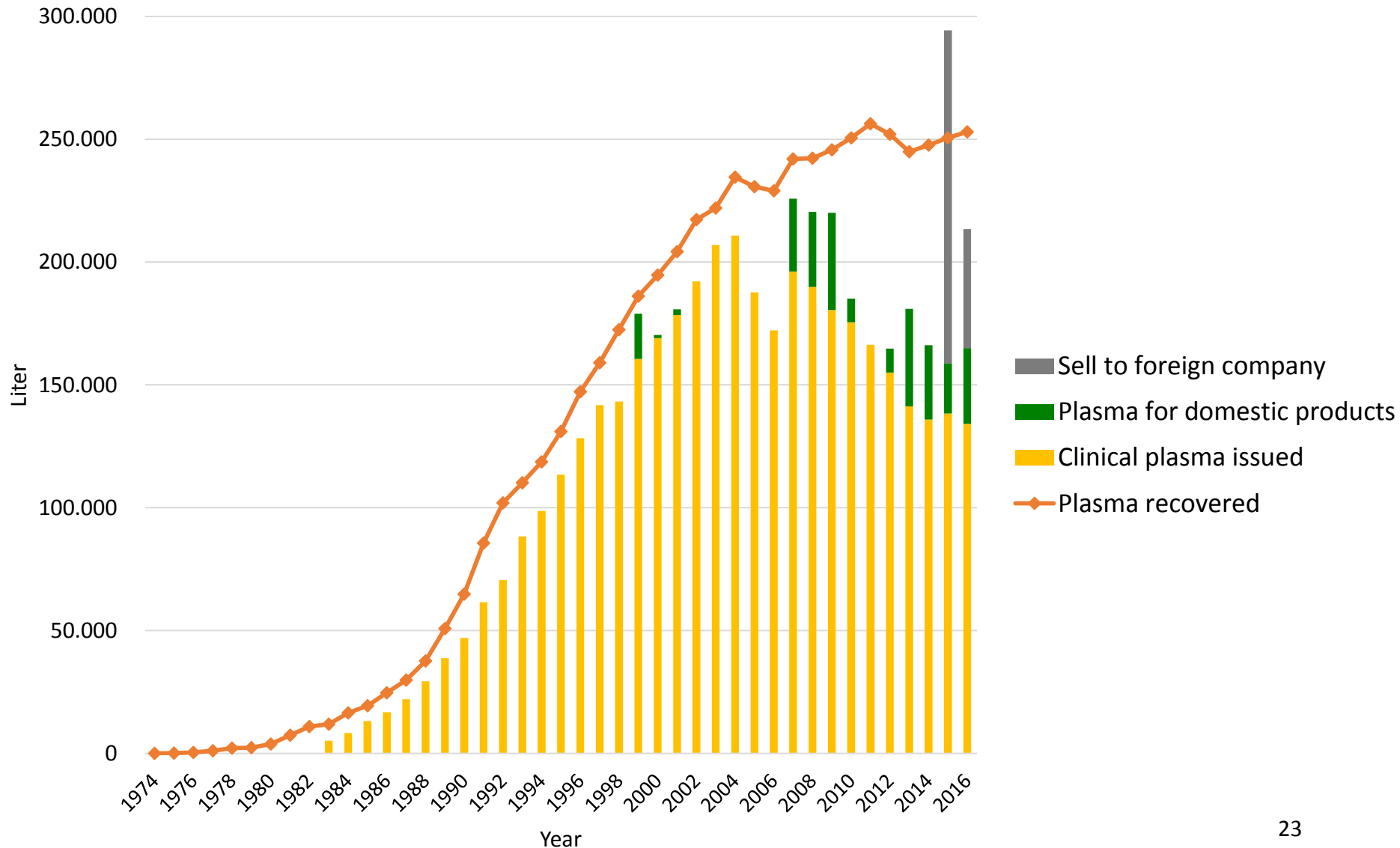
Australian TGA
Integrated
Taiwan cGMP
Standards
Contract
fractionation
agreement
with **CSL**



Role of the Regulatory Agencies in Taiwan



Plasma Recovered, Issued for Clinical Use, and Other Utilization, 1983-2016

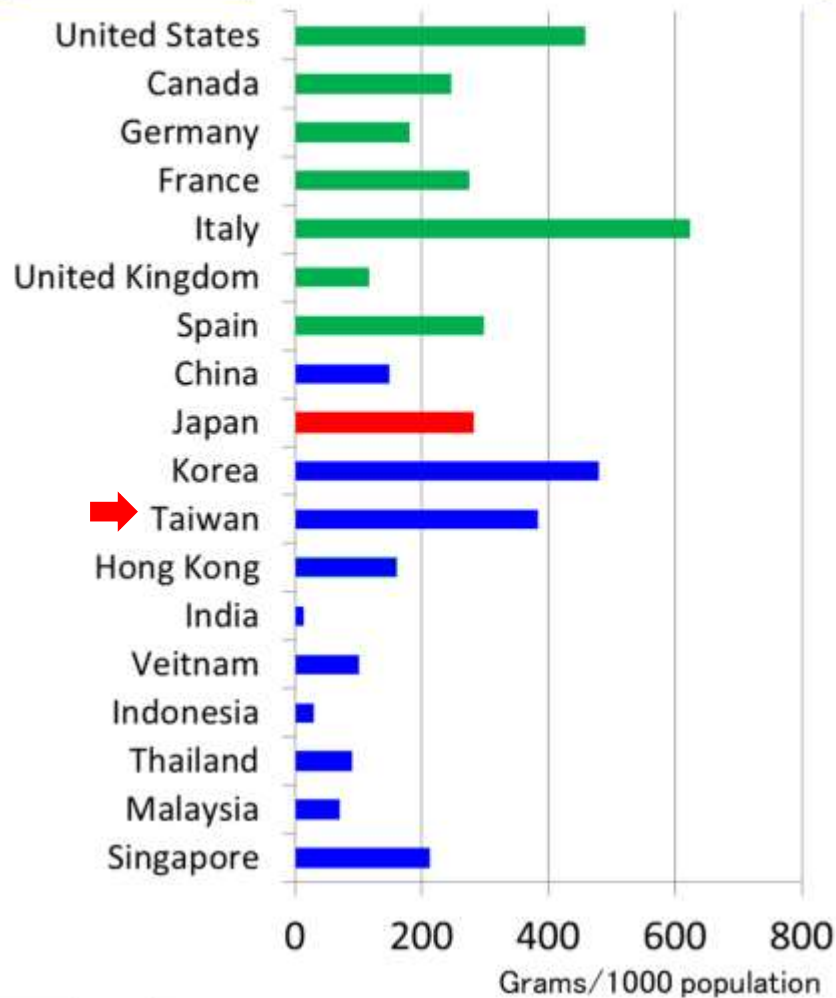


Supply of Plasma Derived Products

<i>Blood products</i>	<i>Domestic need</i>	<i>Description</i>
IVIg	100%	Low patient need because of NHI reimbursement policy
Albumin	10%	
Factor 8	4%	NHI reimburse recombinant blood products
Factor 9	13%	

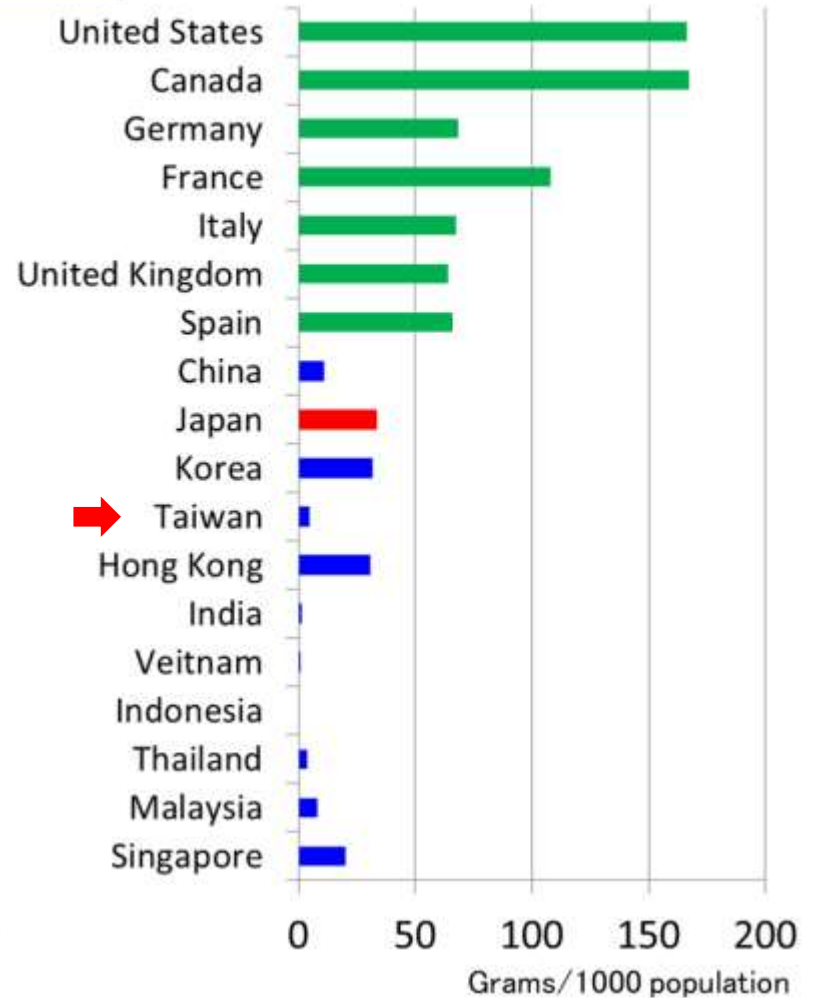
Consumption of Albumin & IGIV

Albumin



IGIV

(source: the Marketing Research Bureau)

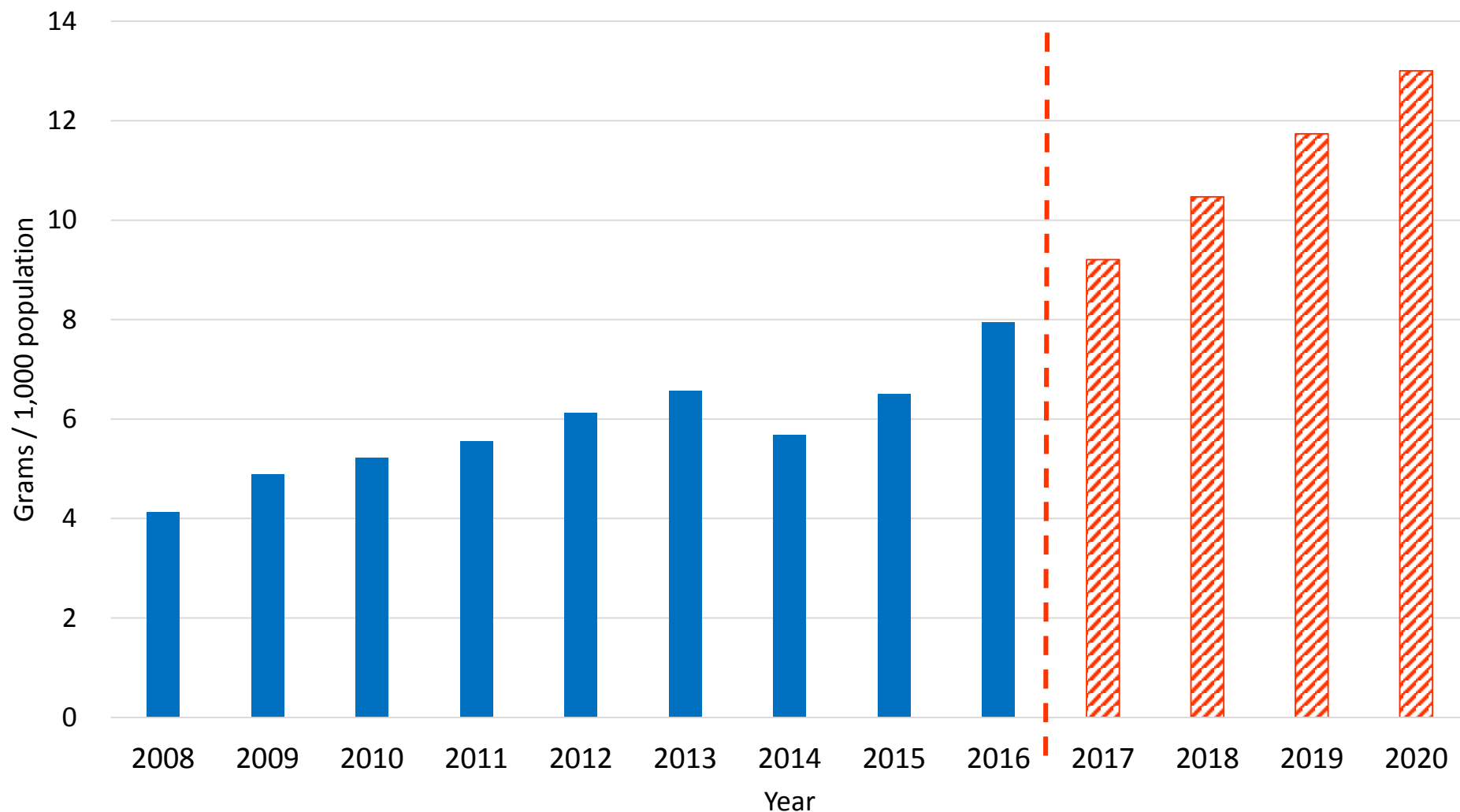


Reference: 5th Bioplasma World Asia 2016, The Key Elements for Self-sufficiency of Plasma-derived Products by Japan Blood Products Organization

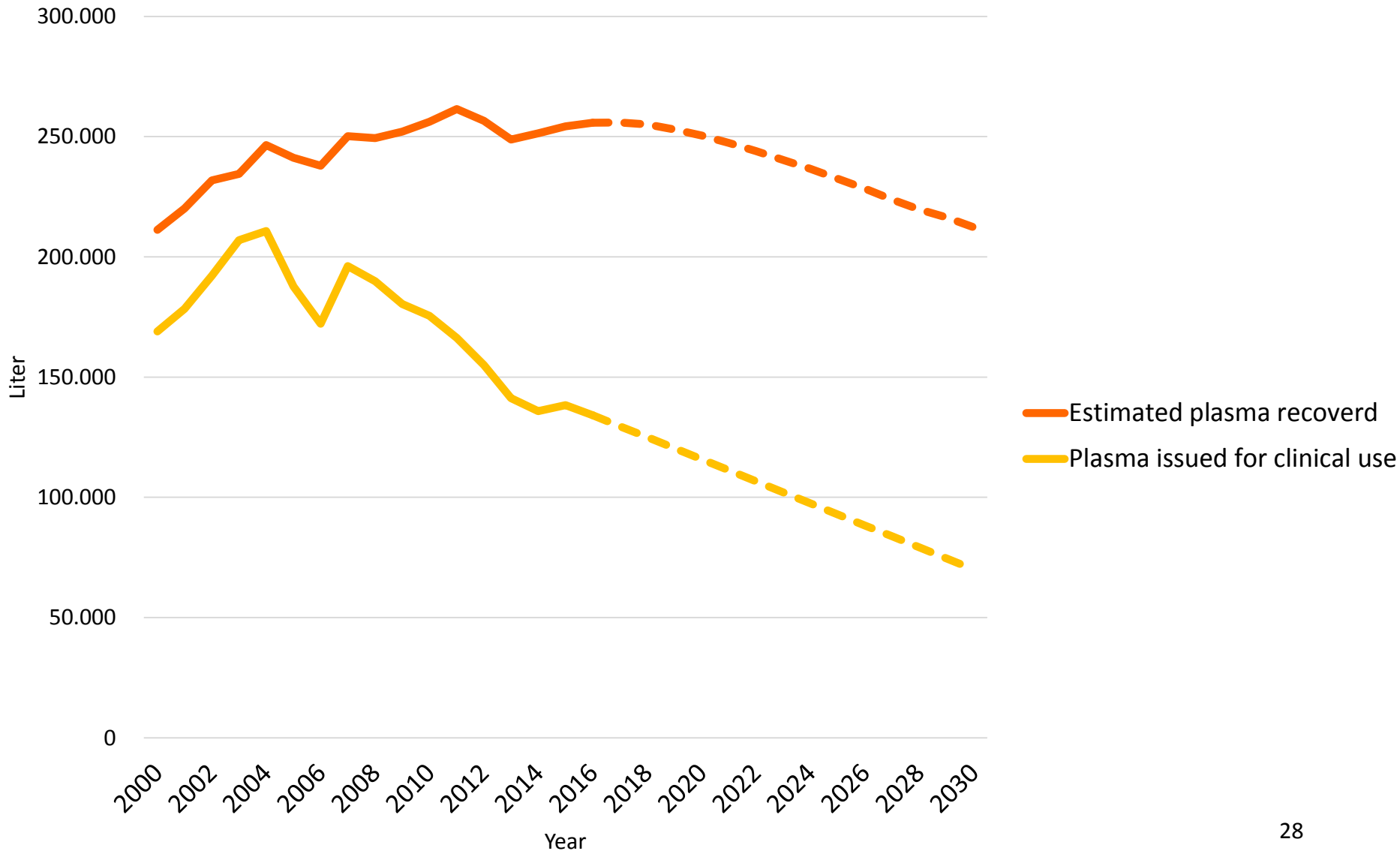
Indication of IVIg by Taiwan NHI

National Health Insurance Indication		NHI
Major IVIg-prescribed Usage	Minor IVIg-prescribed Usage	Not Indicated
<ol style="list-style-type: none"> 1. Acquired Hypogammaglobulinemia secondary to Hematological Malignancy 2. Secondary Immunodeficiency with severe infection 3. Adult Immune Thrombocytopenia with life-threatening bleeding or planned surgery 4. Primary Immunodeficiency with severe infection 	<ol style="list-style-type: none"> 1. Pediatric Immune Thrombocytopenia with life-threatening bleeding or planned surgery 2. Acute Post-transplantation Rejection 3. Severe Kawasaki disease 4. Severe Enterovirus Encephalitis 	<ol style="list-style-type: none"> 1. Chronic Inflammatory Demyelinating Polyradiculoneuropathy 2. Multifocal Motor Neuropathy 3. Guillain-Barré Syndrome 4. Myasthenia Gravis

Projection of IVIg Utilization, 2017-2020, Taiwan



Projection of Plasma Recovered and Issued for Clinical Use



Imbalance of Needs of Various Blood Products

- Albumin 380 tons of Plasma; 350tons(2020projection)
- IVIg 27 tons (2016); 50 tons (2020 projection)
- Factor VIII <10 tons (96% recombinant product)
- Factor IX <10 tons (87% recombinant product)

- Plasma Recovered 100 tons (2016);
120 tons (2020 projection)
140 tons (2030 projection)

Contract Fractionation of Plasma Derived Products

- Y2000-SNBTS
- Y2007-CSL
- 25-50 Tons per year
(2015-2020)
- Surplus of F8 & F9



Some Strategies by TBSF in 2017-2020

Decrease WB/Red Cell need	PBM program
Decrease Albumin need	Management of liver cirrhosis & nephritis : eradicating HBV and HCV by 2030 in Taiwan
Increase IVIg utilization	TFDA instruction sheet; TNHI reimbursement on off label use ; education of clinicians in Immunology, Neurology, Hematology and Pediatrics
Increase plasma derived FVIII and FIX	TNHI reimbursement policy ; Education of clinicians in Hemophilia care

Prospects of Fractionation of Blood products in 2020, Taiwan

A volume of 50,000 liters plasma to be fractionated for blood products based on the utilization of IVIg, some possible options:

1. Continue the current contract fractionation
2. Intermediates from a domestic bulk plasma fractionator and then contract fractionation for final products
3. Chromatography plasma fractionator
4. Membrane electrophoresis fractionator

Thank you for your attention!

