FTAs and its impact on access to medicines

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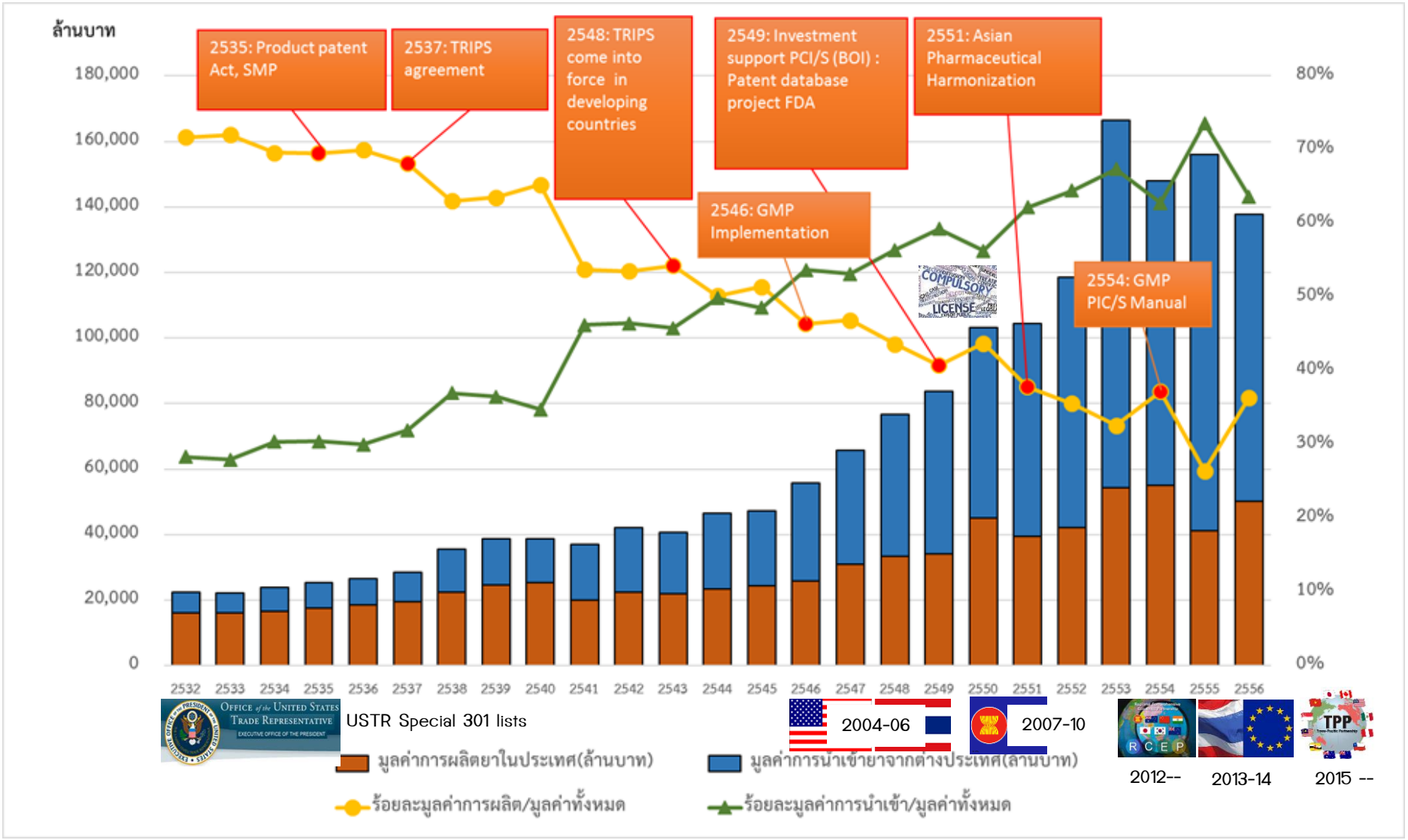
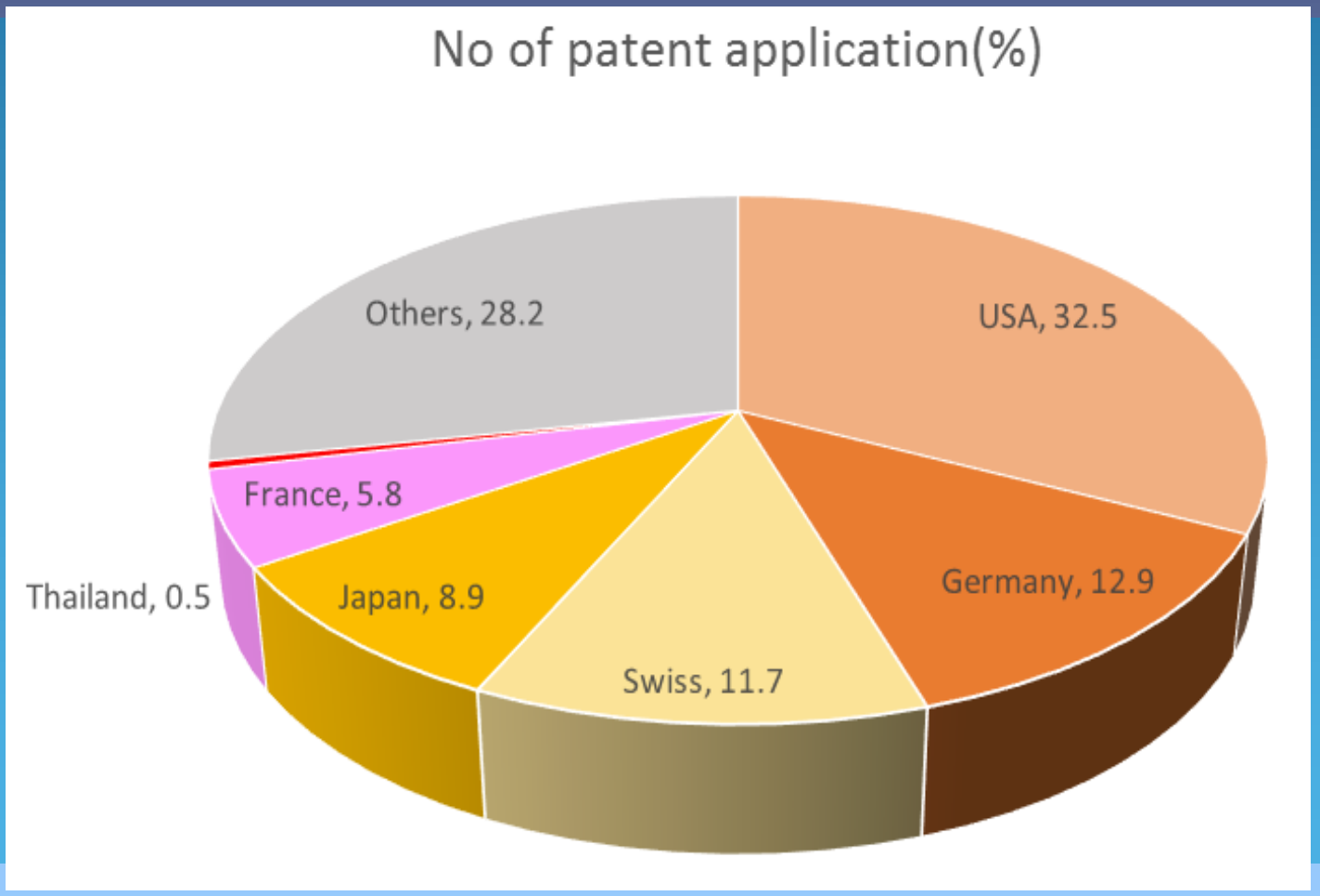
Local production decreased and import increased (Real value of 2013)



Country of origin of patent application (2000-2010)

0.5% from Thailand **72% (1,725/2,188) from developed countries**



(Kessomboon et al, 2012)

TRIPS versus FTAs or TRIPS plus

	WTO (TRIPS)	TRIPS plus: (Thai-US, Thai-EU, TPP)
Patentability	No patents required on plants and animals, No evergreening	Patents on plants, animals, evergreening (US,EU,TPP)
Patent duration	20 years	Patent term extensions (US,EU,TPP)
Data exclusivity	Not required	>= 5 years (US,EU,TPP)
Patent - Regis Linkage	Not required	Required (US, TPP)
TRIPS flexibilities	Compulsory licensing	Weakening CL (US,EU,TPP)

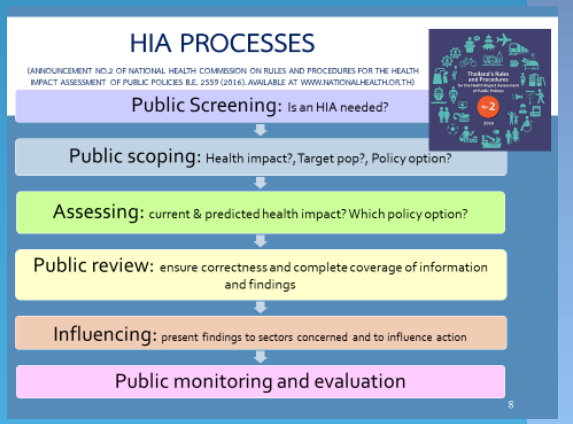
Lessons learned

- Impact assessment approach
- Methods

Impact assessment approach

- Thai-US FTA: research based by experts
- Thai-EU and TPP:

  Health Impact Assessment as a part of the negotiation team



HIA PROCESSES

(ANNOUNCEMENT NO.2 OF NATIONAL HEALTH COMMISSION ON RULES AND PROCEDURES FOR THE HEALTH IMPACT ASSESSMENT OF PUBLIC POLICIES B.E. 2559 (2016). AVAILABLE AT WWW.NATIONALHEALTH.OR.TH)

Public Screening: Is an HIA needed?

↓

Public scoping: Health impact?, Target pop?, Policy option?

↓

Assessing: current & predicted health impact? Which policy option?

↓

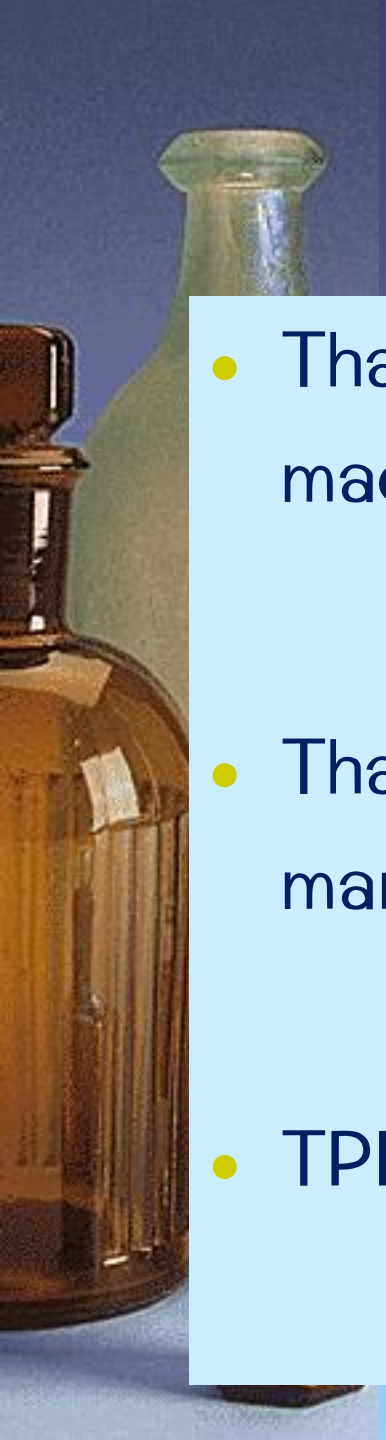
Public review: ensure correctness and complete coverage of information and findings

↓

Influencing: present findings to sectors concerned and to influence action

↓

Public monitoring and evaluation



Methods

- Thai-US FTA: Pharm expenditure? using macro modelling

  Chutima *et al* (2005) and Jiraporn *et al* (2008)

- Thai-EU FTA: Pharm exp, new generic market, IPR border measures?

  using mixed methods

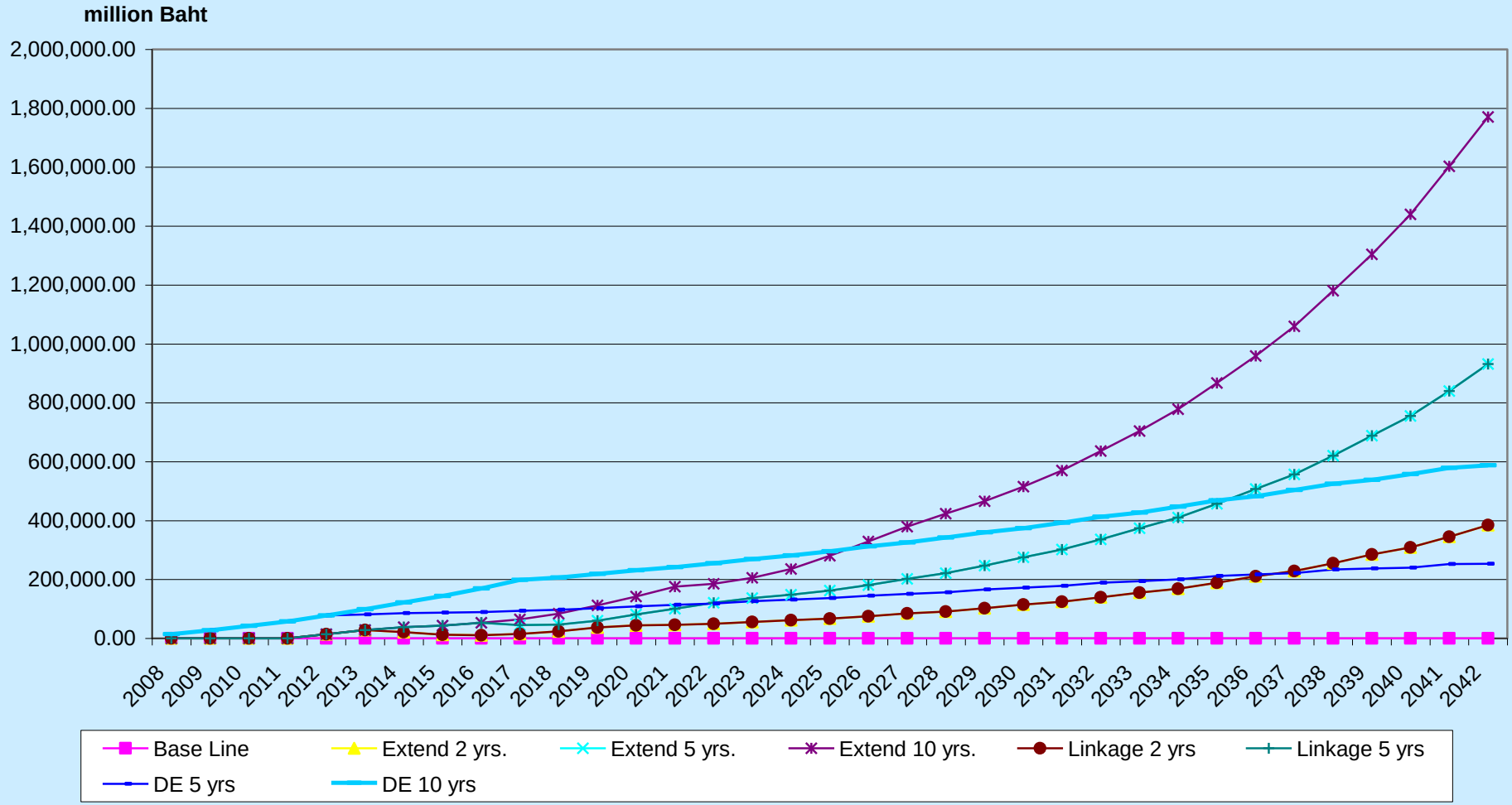
- TPP: Local manufacturing

  using mixed methods (Rungpetch et al 2017)

Thai-US FTAs: Chutima Akaleephan *et al* (2005)

Years of extension	Additional expense per item (mUSD)		Additional expenses of 60 items (1 year) (mUSD)	
	min	max	min	max
1	0.1	1.1	6.4	65.9
2	0.6	2.5	34.2	152.4
3	1.1	4.7	64.8	279.2
4	1.7	7.2	103.9	431.0
5	2.5	12.0	151.7	722.5
6	3.4	19.2	204.5	1151.9
7	4.5	29.3	272.3	1755.9
8	6.7	43.2	403.3	2593.9
9	9.4	62.3	565.0	3737.2
10	13.9	90.2	836.7	5411.4

Thai-US FTAs: Jiraporn Limpananont *et al* (2008)



HIA-TPP PROCESSES

(ANNOUNCEMENT NO.2 OF NATIONAL HEALTH COMMISSION ON RULES AND PROCEDURES FOR THE HEALTH IMPACT ASSESSMENT OF PUBLIC POLICIES B.E. 2559 (2016). AVAILABLE AT WWW.NATIONALHEALTH.OR.TH)

Public Screening: Is an HIA needed?

↓

Public scoping: Health impact?, Target pop?, Policy option?

↓

Assessing: current & predicted health impact? Which policy option?

↓

Public review: ensure correctness and complete coverage of information and findings

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Influencing: present findings to sectors concerned and to influence action

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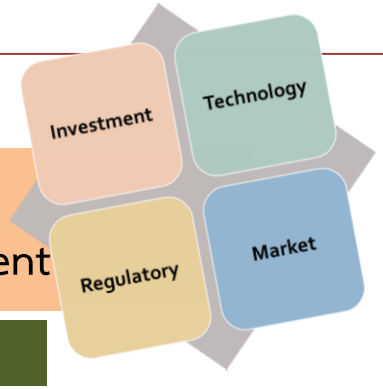
Public monitoring and evaluation

TPP assessment methods: 3 case studies (mixed methods)



1. Explore challenges in pharm supply chain management

R&D and clinical trials

Improve eff: Patent

Manufacturing

Improve eff: Registration

Pricing

Selection

Procurement & import

Distribution

Inspection

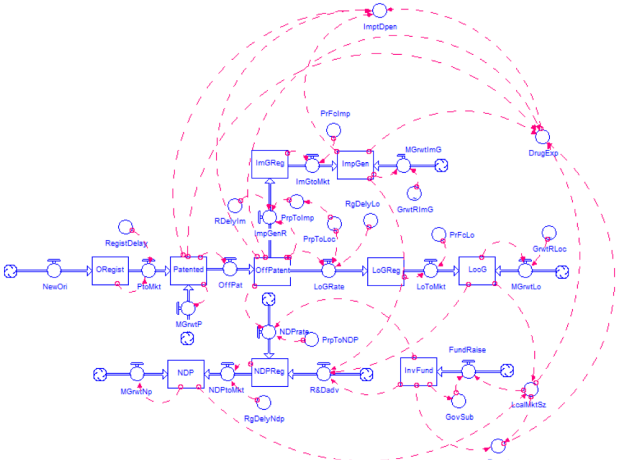
Prescription

Dispensing

Patient

2. Cost benefits analysis:
3 cases
(local manufacturer, societal per.)

3. Impact: compare
Join and ignore TPP



Fixed cost of Biosimilar Bevacizumab

Yr	Proposal (B)	R&D (B)	Formula-tion (B)	Building & machines (B)	Clinical study (B)	Registra-tion (B)	Total (B)
1	500,000	360,000,000					370,500,000
2		144,000,000		328,187,500			472,187,500
3		216,000,000		109,975,938			325,975,938
4				1,001,440,000	480,000,000		1,481,440,000
5			900,000,000	1,323,701,875			2,223,701,875
6				468,569,688	480,000,000		948,569,688
7					1,100,000,000		1,100,000,000
8					1,100,000,000		1,100,000,000
9					1,100,000,000		1,100,000,000
10						120,000,000	120,000,000
	500,000	720,000,000	900,000,000	3,231,875,001	4,260,000,000	120,000,000	9,242,375,001

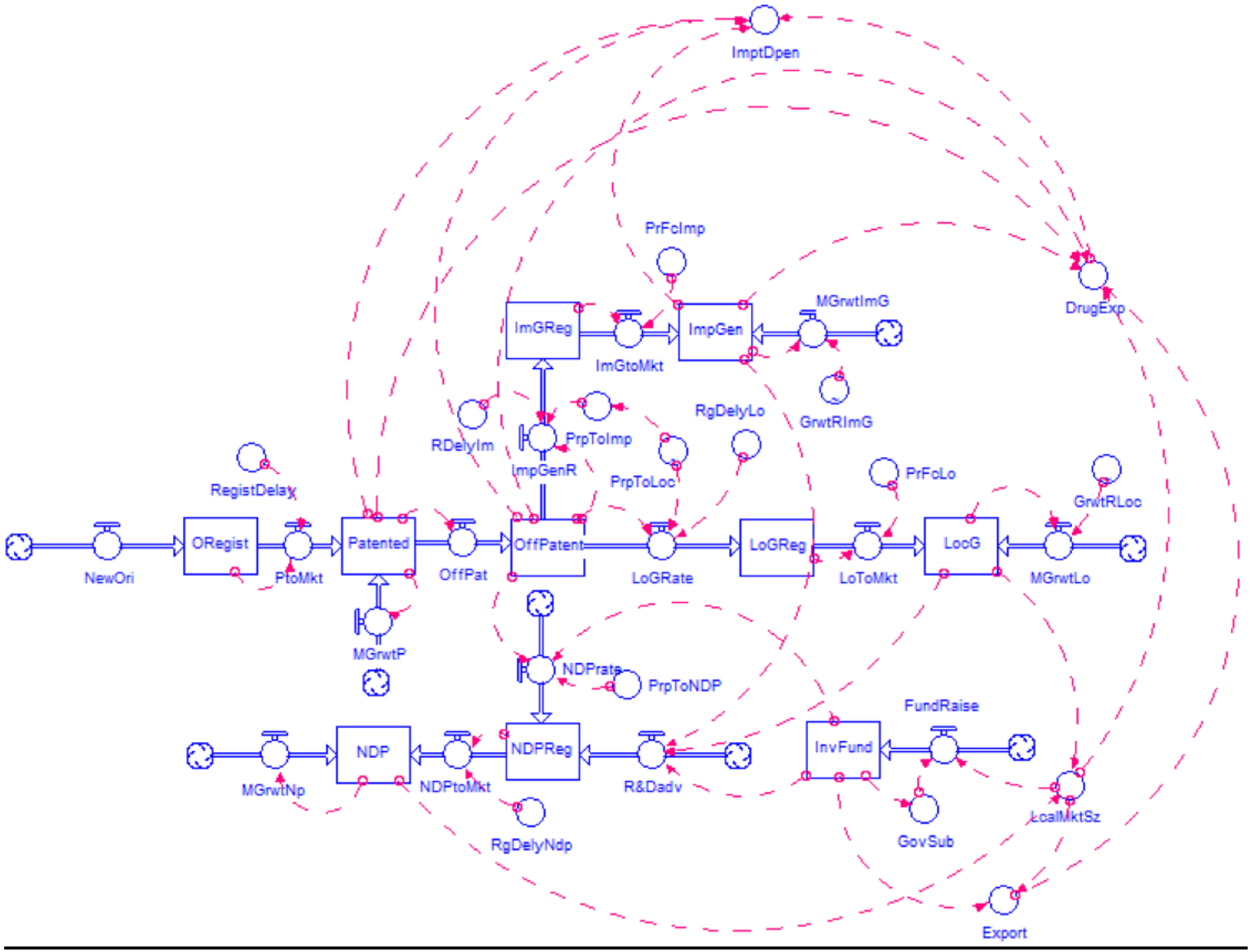
NPV (manufacturer) of Bevacizumab (biosimilar)

Yr	Fixed cost (B)	Variable cost (B)	Sale (B)	Net Present Value (B)
1	31,035,518	-	-	-31,035,518
2	69,788,337	-	-	-69,788,337
3	96,565,403	-	-	-96,565,403
9	741,178,878	-	-	-741,178,878
10	748,882,891	-	-	-748,882,891
11	748,882,891	2,771,773,704	4,750,295,553	1,229,638,958
24	7,704,013	3,678,065,132	6,303,507,540	2,617,738,395
25	7,704,013	3,758,982,565	6,442,184,706	2,675,498,128
26	-	3,841,680,182	6,583,912,770	2,742,232,588
27	-	3,926,197,146	6,728,758,851	2,802,561,705
28	-	4,012,573,483	6,876,791,545	2,864,218,063
29	-	4,100,850,099	7,028,080,959	2,927,230,860
30	-	4,191,068,802	7,182,698,740	2,991,629,939
	10,337,828,947	68,704,482,348	117,746,480,001	38,704,168,706

NPV (societal per.) of Bevacizumab (biosimilar)

Yr	Fixed cost (B)	Export (B)	Decreased import (B)	Gov purchasing (บาท)	Increased patient productivity (B)	NPV (B)
1	31,035,518	-	-	-	-	-31,035,518
2	69,788,337	-	-	-	-	-69,788,337
3	96,565,403	-	-	-	-	-96,565,403
9	741,178,878	-	-	-	-	-741,178,878
10	748,882,891	-	-	-	-	-748,882,891
11	748,882,891	3,815,963,290	756,970,346	934,332,263	33,997,477	2,923,715,959
24	7,704,013	4,733,728,603	1,322,090,573	1,569,778,938	47,330,865	4,525,667,091
25	7,704,013	4,807,108,284	1,380,036,648	1,635,076,422	48,593,543	4,592,958,041
26	-	4,880,610,600	1,440,522,448	1,703,302,170	49,895,923	4,667,726,800
29	-	5,101,087,156	1,638,355,952	1,926,993,803	54,054,810	4,866,504,115
30	-	5,174,283,897	1,710,163,662	2,008,414,843	55,529,771	4,931,562,486
	10,337,828,947	89,699,896,580	23,458,106,126	28,046,583,421	875,564,223	75,649,154,561

Systems dynamic modelling



TPP impact on local manufacturing

- Market exclusivity extension 11 yrs
- Government measures: shorten market registration period, technology support and marketing

Outputs	yr 2555	Not join TPP at yr 2580	Join TPP at yr 2580	Join TPP with measures at yr 2580
Pharm expenditure (mB)	161,960	802,440	929,100	885,140
Importation ratio	73.05%	84.64%	86.91%	77.19%
Local pharm market value (mB)	48,500	136,970	135,150	224,380

Government measures

Outputs	Yr 2555	M1 regulation	M2 technology	M3 invest
Pharm expenditure (mB)	802,440	801,760	734,890	866,850*
Importation ratio	84.64%	84.62%	72.21%	61.22%
Local pharm market value (mB)	136.97	136.98	226.93	840.50
Export (mB)	13,700	13,700	22,690	504,300

* Export 60% of local production value including new drug product

Recommendations

- Health Impact Assessment approach
- Mixed methods
- Strengthening local pharm industry aimed at new drug product and biosimilar

Thank you