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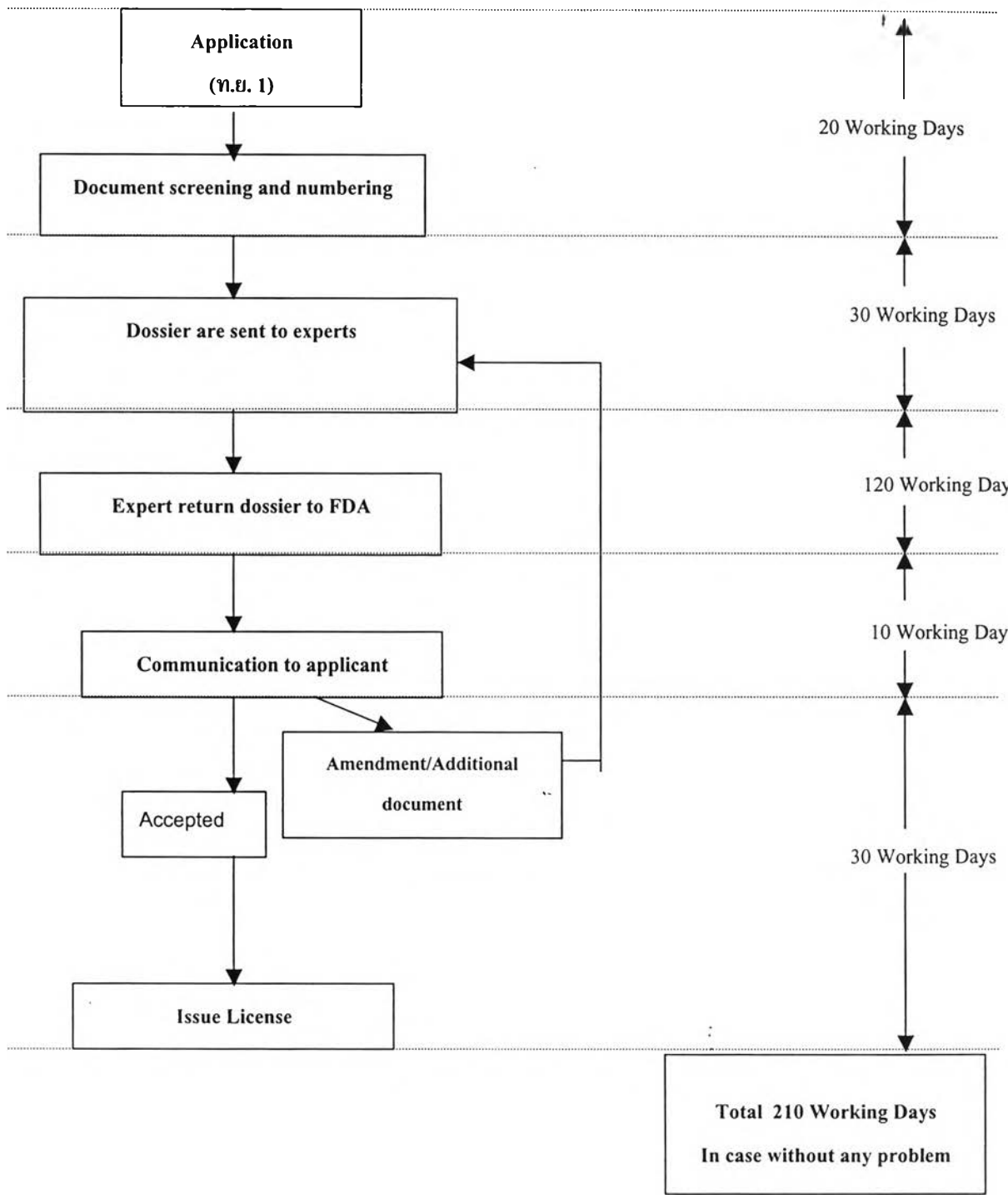
APPENDICES

APPENDIX A: New Drug Registration Process

Channel 1

Conventional Channel: Standard Review

Without sub-committee's review

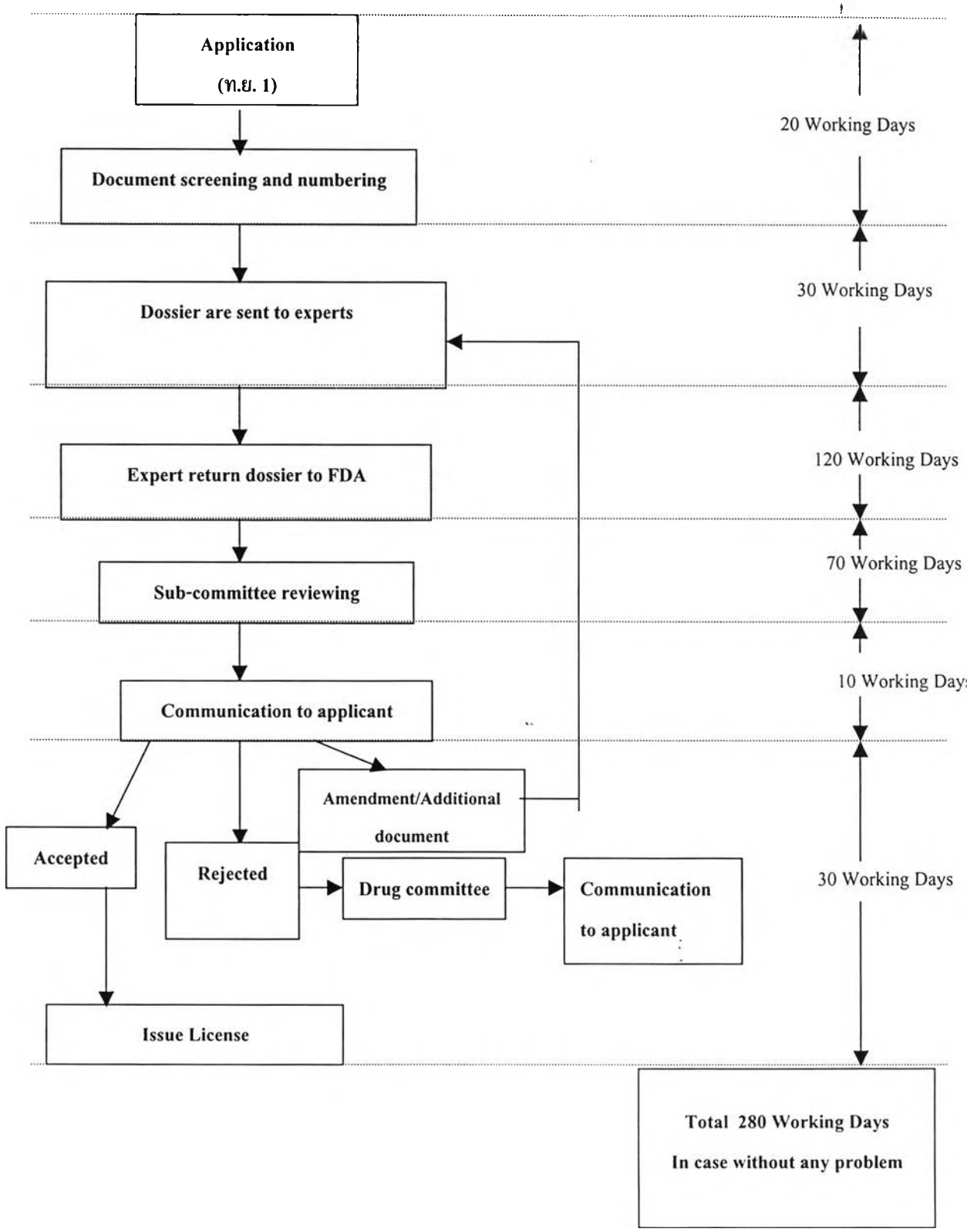


New Drug Registration Process

Channel 1

Conventional Channel: Standard Review

With sub-committee's review

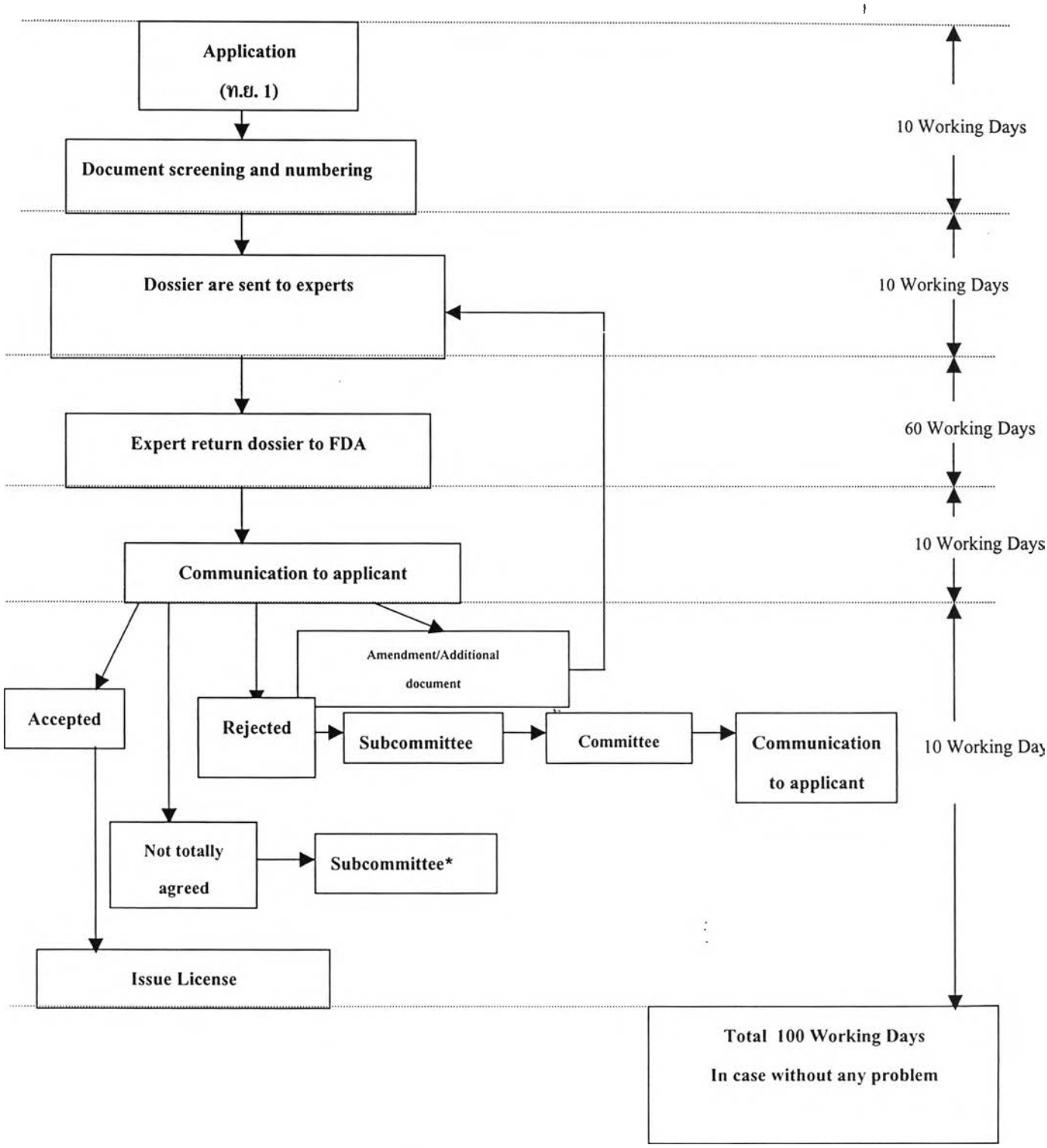


New Drug Registration Process

Channel 2

Accelerated or Priority Review

Case 1



* Just for some cases i.e.; apply → issue license

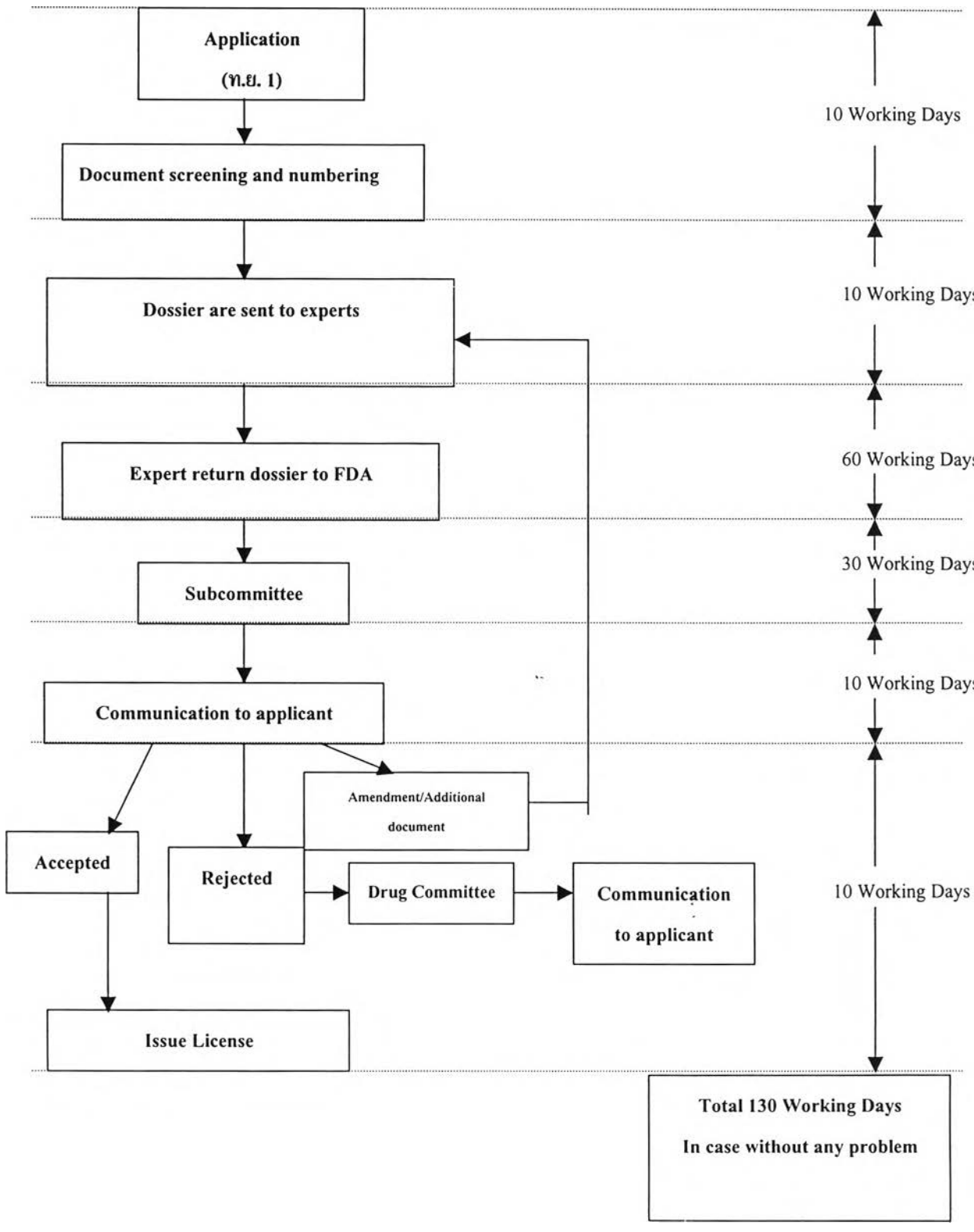
Rejected → Committee → Amendment/Additional

New Drug Registration Process

Channel 2

Accelerated or Priority Review

Case 2



APPENDIX B

Semi-interview Contents

1. Work experiences; to probe details about employment, task and responsibility.
2. Experiences related to the SMP; to probe details of role and responsibility relating to the SMP.
3. Structure, roles of each organization involving in the SMP; to probe details of organization structure and process in performing the activities related to the SMP.
4. Problems found in the SMP system; to probe details of problems listed by the informants using structure, process, and outcome model to guide the issues, and also to prioritize the listed problems.
5. How to solve those problems; to probe tools or techniques or procedures the informants used to solve the problems, as well as the feasibility of handling such problems based on their experiences.

APPENDIX C

ADR Types and Seriousness Associating with Coxibs (1999- September 2004)

No.	ADR Type	Serious (n=101)	Non-serious (n=581)	Total (N=682)
	not defined	-	4	4
1	ABDOMINAL PAIN	1	8	9
2	ACNE	-	1	1
3	ANAEMIA	1	-	1
4	ANAESTHESIA MOUTH	-	1	1
5	ANAPHYLACTIC REACTION	-	1	1
6	ANAPHYLACTIC SHOCK	-	1	1
7	ANAPHYLACTOID REACTION	-	1	1
8	ANGIOEDEMA	2	14	16
9	ATAXIA	-	1	1
10	BACK PAIN	-	1	1
11	BRADYCARDIA	1	-	1
12	BRONCHOSPASM	2	6	8
13	BRUISE	-	1	1
14	BURN	-	1	1
29	DERMATITIS HERPETIFORMIS	1	1	2
30	DIARRHOEA	-	2	2
31	**DIZZINESS**	**3**	17	20
32	DRUG ERUPTION	-	4	4
33	DYSPEPSIA	1	2	3
34	**DYSPNOEA**	**3**	23	26
35	ECZEMA	-	1	1
36	ERYTHEMA ANNULARE	-	1	1
37	ERYTHEMA MULTIFORME	2	4	6
38	EXANTHEMA	-	1	1
39	EXTRAPYRAMIDAL DISORDER	-	1	1
40	EYE ABNORMALITY	-	1	1
41	EYELID OEDEMA	-	3	3
42	**FACE OEDEMA**	**4**	**32**	**36**
43	FATIGUE	1	3	4
44	FEVER	-	4	4
45	FIXED ERUPTION	1	1	2

ADR Types and Seriousness Associating with Coxibs (1999- September 2004) (Continue.)

No.	ADR Type	Serious (n=101)	Non-serious (n=581)	Total (N=682)
46	FLATULENCE	1	-	1
47	FLUSHING	-	1	1
48	GASTRIC ULCER	1	-	1
49	GASTROENTERITIS	1	-	1
50	GASTRO-INTESTINAL DISORDER NOS	1	-	1
51	**GI HAEMORRHAGE**	**3**	-	3
52	HALLUCINATION	-	1	1
53	**HEADACHE**	**3**	4	7
54	HEPATITIS	1	-	1
55	HICCUP	-	2	2
56	HOT DRY SKIN	1	2	3
57	HOT FLUSHES	1	1	2
58	HYPERTENSION	-	1	1
59	HYPOKINESIA	-	1	1
60	**HYPOTENSION**	**3**	1	4
61	ILLUSION	-	1	1
62	INSOMNIA	-	3	3
63	ITCHING	2	3	5
64	LEG PAIN	1	-	1
65	LEUKORRHOEA	-	1	1
66	MACULAR RASH	-	1	1
67	MOUTH DRY	1	2	3
68	MUSCLE WEAKNESS	-	2	2
69	NAUSEA	2	22	24
70	NEUROPATHY	-	1	1
71	OEDEMA	2	9	11
72	OEDEMA GENERALISED	1	5	6
73	OEDEMA LEGS	-	10	10
74	OEDEMA MOUTH	-	11	11
75	OEDEMA PERIORBITAL	-	15	15
76	OEDEMA PERIPHERAL	1	1	2

ADR Types and Seriousness Associating with Coxibs (1999- September 2004) (Continue.)

No.	ADR Type	Serious (n=101)	Non-serious (n=581)	Total (N=682)
77	PAIN	-	2	2
78	PALPITATION	2	12	14
79	PAPULAR RASH	-	2	2
80	PARAESTHESIA	-	1	1
81	PERIPHERAL ISCHAEMIA	-	1	1
82	PETECHIAE	-	1	1
83	PHOTOSENSITIVITY ALLERGIC REACTION	-	1	1
84	**PRURITUS**	**7**	**87**	**94**
85	PULMONARY OEDEMA	1	-	1
86	**RASH**	**6**	**79**	**85**
87	**RASH ERYTHEMATOUS**	**6**	**42**	**48**
88	RASH FOLLICULAR	-	1	1
89	**RASH MACULO-PAPULAR**	**4**	**34**	**38**
90	RASH PURPURIC	-	1	1
91	RENAL FAILURE ACUTE	1	-	1
92	RIGORS	-	1	1
93	SKIN EXFOLIATION	-	1	1
94	SOMNOLENCE	-	2	2
95	**STEVENS JOHNSON SYNDROME**	**9**	2	11
96	STOMATITIS ULCERATIVE	-	2	2
97	STOOL BLACK	1	-	1
98	SWELLING NON-INFLAMMATORY	-	1	1
99	SYNCOPE	-	2	2
100	TACHYCARDIA	-	2	2
101	THIRST	-	1	1
102	THROAT TIGHTNESS	-	1	1
103	THROMBOCYTOPENIA	1	-	1
104	TONGUE DISORDER	1	-	1
105	TOXIC EPIDERMAL NECROLYSIS	1	-	1
106	**URTICARIA**	**3**	30	33
107	URTICARIA ACUTE	-	1	1

Types and Seriousness Associating with Coxibs (1999- September 2004) (Continue.)

No.	ADR Type	Serious (n=101)	Non-serious (n=581)	Total (N=682)
108	UTERINE SPASM	-	1	1
109	VERTIGO	-	1	1
110	VESICULAR ERUPTION	-	1	1
111	VESICULAR RASH	-	1	1
112	VISION ABNORMAL	-	2	2
113	VOMITING	2	11	13
114	WHEEZES	-	1	1

APPENDIX D

ADRs of Statins by Seriousness of ADRS (1993-September 2004)

No.	ADR Type	(n=133) Serious	(n=514) Non-serious	(N=647) Total
	No defined data	-	67	67
1	ABDOMINAL DISCOMFORT	-	2	2
2	ABDOMINAL DISTENSION	1	-	1
3	ABDOMINAL PAIN	1	8	9
4	AGRANULOCYTOSIS	-	1	1
5	ALOPECIA	-	3	3
6	ANAEMIA	-	3	3
7	ANAESTHESIA LIP	-	1	1
8	ANAESTHESIA LOCAL	-	1	1
9	ANAESTHESIA MOUTH	-	1	1
10	ANAPHYLACTIC REACTION	-	1	1
11	ANAPHYLACTIC SHOCK	1	-	1
12	ANAPHYLACTOID REACTION	1	1	2
13	ANAPHYLAXIS	1	-	1
14	ANGIOEDEMA	3	3	6
15	ANOREXIA	1	4	5
16	ARRHYTHMIA	-	1	1
17	ATAXIA	-	1	1
18	BACK PAIN	-	2	2
19	BLEEDING TIME INCREASED	-	1	1
20	BLEEDING VARICOSE VEIN	1	-	1
21	BRADYCARDIA	2	3	5
22	BRONCHOSPASM	-	1	1
23	BULLOUS ERUPTION	-	1	1
24	CHEILITIS	-	1	1
25	CHEST PAIN	1	-	1
26	CONFUSION	1	-	1
27	CONGESTIVE HEART FAILURE	1	-	1
28	CONJUNCTIVITIS	1	-	1
29	CONVULSIONS	1	2	3
30	COUGHING	3	**28**	**31**
31	CRAMPS	-	1	1
32	CUSHING'S SYNDROME	1	-	1

ADRs of Statins by Seriousness of ADRS (1993-September 2004) (Continue.)

No.	ADR Type	(n=133) Serious	(n=514) Non-serious	(N=647) Total
33	DELIRIUM	-	1	1
34	DERMATITIS	-	1	1
35	DERMATITIS EXFOLIATIVE	2	1	3
36	DIARRHOEA	3	2	5
37	DIARRHOEA BLOODY	1	-	1
38	DIZZINESS	2	16	18
39	DREAMING ABNORMAL	-	1	1
40	DYSPEPSIA	-	4	4
41	DYSPNOEA	3	7	10
42	DYSURIA	-	1	1
43	ECZEMA	-	1	1
44	EPISTAXIS	2	-	2
45	ERYTHEMA MULTIFORME	2	2	4
46	EYELID OEDEMA	-	1	1
47	FACE OEDEMA	1	5	6
48	**FATIGUE**	**3**	13	16
49	FEVER	1	3	4
50	FIXED ERUPTION	-	3	3
51	FLATULENCE	2	3	5
52	FLUSHING	-	1	1
53	GASTRIC ULCER	1	-	1
54	GASTRITIS	-	5	5
55	GI HAEMORRHAGE	1	3	4
56	GYNAECOMASTIA	-	2	2
57	HAEMATURIA	1	3	4
58	HAEMOPTYSIS	1	-	1
59	HEAD REVOLVING AROUND	-	1	1
60	**HEADACHE**	3	**22**	25
61	HEART FAILURE	1	-	1
62	HEPATIC ENZYMES INCREASED	-	2	2
63	HEPATIC FUNCTION ABNORMAL	1	1	2
64	**HEPATITIS**	**5**	1	6
65	HEPATITIS CHOLESTATIC	1	-	1

ADRs of Statins by Seriousness of ADRS (1993-September 2004) (Continue.)

No.	ADR Type	(n=133) Serious	(n=514) Non-serious	(N=647) Total
66	HOT DRY SKIN	-	1	1
67	HOT FLUSHES	-	1	1
68	HYPERGLYCAEMIA	-	1	1
69	**HYPOGLYCAEMIA**	**7**	2	9
70	HYPOKALAEMIA	-	4	4
71	HYPONATRAEMIA	2	1	3
72	HYPOTENSION	-	2	2
73	HYPOTENSION ORTHOSTATIC	-	1	1
74	IMPOTENCE	-	1	1
75	INSOMNIA	-	8	8
76	ITCHING	1	2	3
77	JAUNDICE	2	-	2
78	LEG PAIN	-	1	1
79	LIBIDO DECREASED	-	1	1
80	LIP ULCERATION	-	1	1
81	MALAISE	-	2	2
82	MELAENA	-	1	1
83	**MUSCLE WEAKNESS**	**2**	6	8
84	**MYALGIA**	**7**	15	22
85	MYASTHENIA GRAVIS-LIKE SYNDROME	-	1	1
86	**MYOPATHY**	**5**	6	11
87	MYOSITIS	-	2	2
88	NAEVUS	-	2	2
89	**NAUSEA**	**5**	**24**	**29**
90	NEPHRITIS	1	-	1
91	NEUROPATHY PERIPHERAL	-	1	1
92	OEDEMA	-	5	5
93	OEDEMA GENERALISED	-	1	1
94	OEDEMA LEGS	1	10	11
95	OEDEMA MOUTH	-	1	1
96	OEDEMA PERIORBITAL	-	6	6
97	OEDEMA PHARYNX	-	1	1

ADRs of Statins by Seriousness of ADRS (1993-September 2004) (Continue.)

No.	ADR Type	(n=133) Serious	(n=514) Non-serious	(N=647) Total
98	PAIN	-	2	2
99	PALPITATION	-	10	10
100	PARAESTHESIA	-	2	2
101	PENIS DISORDER	-	1	1
102	PERIPHERAL ISCHAEMIA	-	1	1
103	PETECHIAE	-	3	3
104	PHOTOSENSITIVITY REACTION	-	1	1
105	PILOERECTION	-	1	1
106	**PRURITUS**	**7**	**31**	**38**
107	PURPURA	-	2	2
108	**RASH**	**4**	**27**	**31**
109	RASH ERYTHEMATOUS	2	16	18
110	RASH MACULO-PAPULAR	3	14	17
111	RASH PURPURIC	-	2	2
112	**RENAL FAILURE ACUTE**	**4**	-	4
113	RESPIRATORY DEPRESSION	-	1	1
114	**RHABDOMYOLYSIS**	**7**	-	7
115	**STEVENS JOHNSON SYNDROME**	**10**	2	12
116	SYNCOPE	-	1	1
117	TETANY	-	1	1
118	THROMBOCYTOPENIA	1	-	1
119	TONGUE PARALYSIS	-	2	2
120	TREMOR	-	2	2
121	URINE DISCOLOURATION	-	1	1
122	URTICARIA	-	7	7
123	URTICARIA ACUTE	1	-	1
124	VASCULITIS	-	1	1
125	VERTIGO	-	7	7
126	VOMITING	3	19	22
127	WEAKNESS GENERALIZED	-	1	1
128	WEIGHT INCREASE	-	1	1

APPENDIX E

สำหรับศูนย์เครือข่ายเป็นผู้บันทึก	แบบรายงานอาการอันไม่พึงประสงค์จากการใช้ผลิตภัณฑ์สุขภาพ	สำหรับศูนย์ APR อย. เป็นผู้บันทึก
เลขที่รายงาน ว/ดป/ ที่รับรายงาน	(ข้อมูลทั้งหมดจะเก็บเป็นความลับของทางราชการโดยเฉพาะ) ชนิดรายงาน ☐ ใหม่ ☐ ติดตามผลจากการรายงานเดิม	เลขที่รายงาน ว/ดป ที่รายงาน

ข้อมูลเกี่ยวกับผู้ป่วย

เลขที่ผู้ป่วย ☐ HN ☐ AN	ประเภท	เพศ	อายุ	เคยมีประวัติการแพ้ผลิตภัณฑ์หรือไม่ ☐ ไม่มี ☐ มี (ระบุ).....
ชื่อ- นามสกุล	☐ ผู้ป่วยใน ☐ ผู้ป่วยนอก	☐ ชาย ☐ หญิง		ภาวะอื่นๆของผู้ป่วย ที่เกี่ยวข้อง

ข้อมูลเกี่ยวกับผลิตภัณฑ์สุขภาพ

ประเภทของผลิตภัณฑ์ ☐ ยา ☐ ยาใหม่(SMP) ☐ อาหาร ☐ เครื่องสำอาง ☐ เครื่องมือแพทย์ ☐ วัตถุอันตราย

ชื่อผลิตภัณฑ์ (ชื่อสามัญ / ชื่อทางการค้า) (ระบุชื่อผู้ผลิต/ผู้จำหน่าย/Lot No. กรณีทราบ)	* S.O I	ขนาดและวิธีใช้ (ความแรง,ปริมาณ,หน่วย,ความถี่,วิธีใช้)	ว/ดป ที่เริ่มใช้	ว/ดป ที่หยุดใช้	โรคหรือสาเหตุที่ใช้ผลิตภัณฑ์และ ICD CODE (กรณีทราบ)

* S = Suspected product หมายถึงผลิตภัณฑ์ที่ต้องสงสัย. O = Other product หมายถึง ผลิตภัณฑ์ที่ใช้ร่วม

I = Product interaction หมายถึง การเกิดปฏิกิริยาต่อกันของผลิตภัณฑ์

ข้อมูลเกี่ยวกับอาการไม่พึงประสงค์

อาการอันไม่พึงประสงค์ที่พบ (ระบุ WHO Adverse Reactions Terms กรณีทราบ)	ICD CODE (กรณีทราบ)	ดำความผิดปรกติทางห้องปฏิบัติการและผลการตรวจร่างกายที่อาจเป็นผลมาจากการใช้ผลิตภัณฑ์ที่สงสัย
ว/ดป ที่เริ่มอาการ.....		

ระบุความรุนแรงของอาการ (Seriousness)	ภายหลังเกิดอาการอันไม่พึงประสงค์		ผลลัพธ์ (Outcome) ที่เกิดขึ้นภายหลังเกิดอาการไม่พึงประสงค์
○ ไม่ร้ายแรง (Non - serious	○ หยุดใช้ (Dechallenge)	○ ทดลองซ้ำ (Rechallenge)	☐ 1. หายเป็นปรกติโดยไม่มีร่องรอยเดิม
○ ร้ายแรง (Serious) คือ	☐ 1. อาการดีขึ้นอย่างชัดเจน (Definite Improvement)	☐ 1. เกิดอาการเดิมซ้ำขึ้นอีก (Recurrence of symptoms)	☐ 2. หายโดยมีร่องรอยเดิม
☐ 1. Death (ระบุ ว/ดป)....	☐ 2 อาการไม่ดีขึ้น (No recurrence)	☐ 2. ไม่เกิดอาการซ้ำ (No recurrence)	☐ 3. ยังมีอาการอยู่
☐ 2. Life - Theratening	☐ 3 ไม่ทราบ (Unknown)	☐ 3. ไม่ทราบ (Unknown)	☐ 4. ตาย-เนื่องจากอาการอันไม่พึงประสงค์ ระบุ (ว/ดป).....
☐ 3. Hospitalization - Initial/prolonged	○ ใช้ผลิตภัณฑ์ที่สงสัยต่อไป	○ไม่มีการใช้ซ้ำ (No rechallenge performed)	☐ 5.ตาย-เนื่องจากอาจเกี่ยวข้องกับผลิตภัณฑ์
☐ 4. Disability	☐ 1. ใช้ต่อขนาดเดิม		☐ 6.ตาย-เนื่องจากสาเหตุอื่นไม่เกี่ยวข้องกับผลิตภัณฑ์ (ระบุสาเหตุ).....
☐ 5. Congenital anomaly	☐ 2. ใช้ต่อแต่ลดขนาดลง		☐ 7. ไม่สามารถติดตามผลได้
☐ 6. Required Intervention to prevent permanent impairment to damage			

ข้อมูลเกี่ยวกับผู้รายงาน

แผนกที่พบผู้ป่วย.....

ชื่อผู้วินิจฉัยอาการ.....

เป็น ☐ แพทย์ ☐ เภสัชกร ☐ พยาบาล ☐ อื่นๆ(ระบุ).....

ชื่อผู้ประเมิน/บันทึกรายการ.....

เป็น ☐ แพทย์ ☐ เภสัชกร ☐ พยาบาล ☐ อื่นๆ(ระบุ).....

ข้อมูลเกี่ยวกับสถานพยาบาลหรือแหล่งที่รายงาน

เลขที่รายงาน..... ว/ดป ที่บันทึกรายงาน.....

ชื่อสถานพยาบาล/แหล่งที่รายงาน.....

จังหวัด.....

ผลการประเมินความสัมพันธ์ของผลิตภัณฑ์กับอาการอันไม่พึงประสงค์

☐ Certain ☐ Probable ☐ Possible ☐ Unlikely

BIOGRAPHY

Miss Yaowalak Amrumpai is a faculty member in the Community Pharmacy department, Silpakorn University, Thailand. After her graduation with Bachelor's degree in Pharmaceutical Sciences from Chulalongkorn University in 1986, Miss Amrumpai had worked at the Ministry of Public Health for 6 years. After moving to Silpakorn University for one year, she enrolled in the graduate study at Mahidol University and received her Master of Science degree in Epidemiology two years later. Miss Amrumpai's interest in drug-related issues had led her to pursue a higher education and research at the Internationl Program in Social and Administrative Pharmacy, Chulalongkorn University. Upon completion of her doctoral degree, she will resume her teaching and research at Silpakorn University. Miss Yaowalak Amrumpai's research interests include various issues in drug system including drug distribution and regulation.