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2022

Quasi-Drug Approval Report

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Ministry of Food and
Drug Safety

Director for Novel Products Approval

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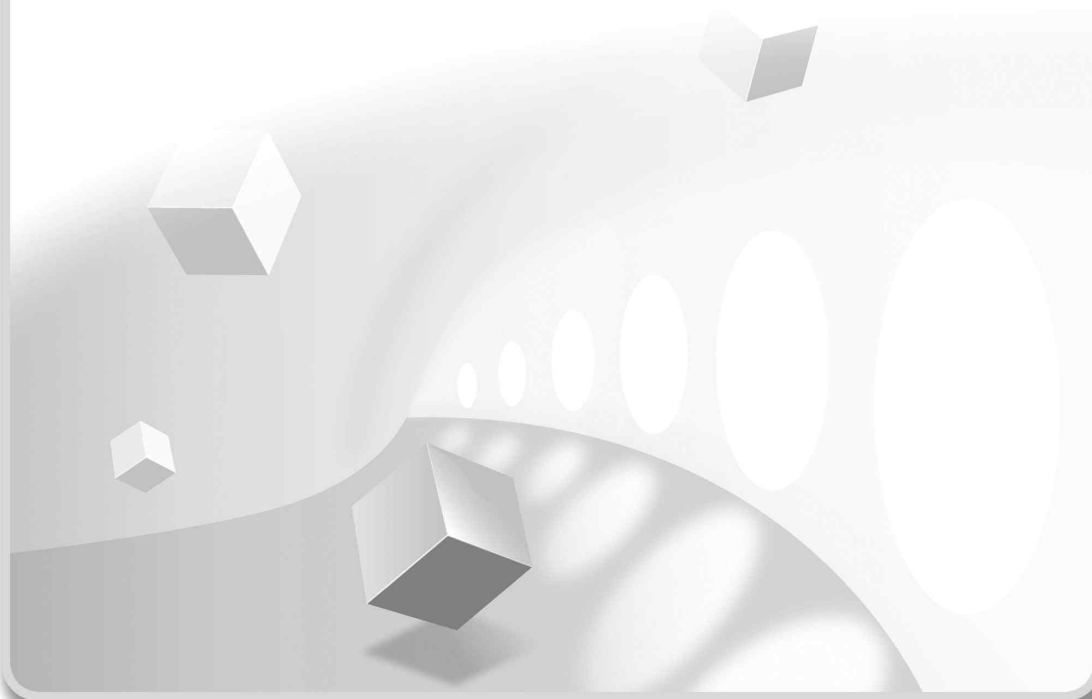
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General Status of Quasi-Drug Approval(Notification) in 2022



1. General Status of Quasi-Drug Approval (Notification) in 2022

This approval report aims to support systematization and efficiency of relevant policy establishment, execution, approval and notification tasks and product development by multilaterally summarizing, analyzing and sharing the quasi-drug manufacturing(import) approval and notification status.

1.1. General Status

There are a total of 2,029 items in quasi-drug manufacturing(import) approval and notification in 2022, which is 3,038 item(60.0%) decrease from 5,067 items in 2021.

Among them, there are 1,937 items (95.5%) in manufacturing and 92 items (4.5%) in import, which means that domestic manufacturing items are 21 times more than import items. There were 1,497 items(73.8%) in approval and 531 items(26.2%) in notification, which means that the number of approval is 2.8 times higher.

By institution, 32 items(1.6%) were handled by head office, 1,997 items(98.4%) by local offices, meaning that most items were handled by local offices. When the contents handled by regional offices were analyzed, 1,465 items(73.3%) were approved and 532 items(26.6%) were notified.

Table 1 Quasi-Drug Manufacturing(Import) Approval and Notification Status (2021~2022)

(Unit: Number of Items)

Year	Total	Approval	Notification	Mfg.	Import	Head office	Regional Office
'22	2,029	1,497 (73.8%)	532 (26.2%)	1,937 (95.5%)	92 (4.5%)	32 (1.6%)	1,997 (98.4%)
'21	5,067	4,454 (87.9%)	613 (12.1%)	4,881 (96.3%)	186 (3.7%)	20 (0.4%)	5,047 (99.6%)

* Including cancellation or withdrawal, excluding for export

When comparing the manufacturing(import) approval and notification status of 2022 with those of 2021, 2,957 items(-66.4%) decreased in approval, 3,050 items(-60.4%) decreased in approval and notification of regional offices, 2,944 items(-60.3%) decreased in manufacturing compared to last year.

In addition, when comparing the current status of 2022 in terms of domestic manufacturing and import, most of them corresponded to domestic manufacturing(95.5%), which is similar to those of 2021.

In 2022, the number of quasi-drug manufacturing(import) approval and notification items was 2,029 items. When comparing the number of manufacturing(import) approval and notification items by year for recent 10 years, it maintained about 2,400 items for the period from 2014 ~ 2016, and temporarily decreased to about 1,500 items for the period from 2017~2019, due to transfer to functional cosmetics.

Table 2 Manufacturing(Import) Approval and Notification Status by Year

(Unit: Number of Items)

Classification	2014	2015	2016	2017	2018	2019	2020	2021	2022
Approval	444	420	531	516	693	742	3,576	4,454	1,497 (73.8%)
(Year-on-Year increase %)	-5.4	26.4	-2.8	34.3	7.1	381.9	24.6		-66.4
Notification	1,783	2,046	1,909	1,124	752	628	1,305	613	532 (26.2%)
(Year-on-Year increase %)	14.8	-6.7	-41.1	-33.1	-16.5	107.8	-53.0		-13.2
Total	2,227	2,466	2,440	1,640	1,445	1,370	4,881	5,067	2,029
(Year-on-Year increase %)	10.7	-1.1	-32.8	-11.9	-5.2	256.3	3.8		-60.0

From 2020 to 2021, the number of approval and notification sharply increased to about 5,000 items. In 2022, it was about 2,000 items, showing similar number of quasi-drug manufacturing(import) approval and notification items.

The increase in number of items from 2020 to 2021 is due to significant increase in national demands for quasi-drug such as masks and external disinfectants, following outbreak of Covid 19 pandemic. This increase trend returned to the pre-Covid 19 level in 2022, due to stabilization of supply of quarantine products to markets as well as easing of mandatory mask wearing.

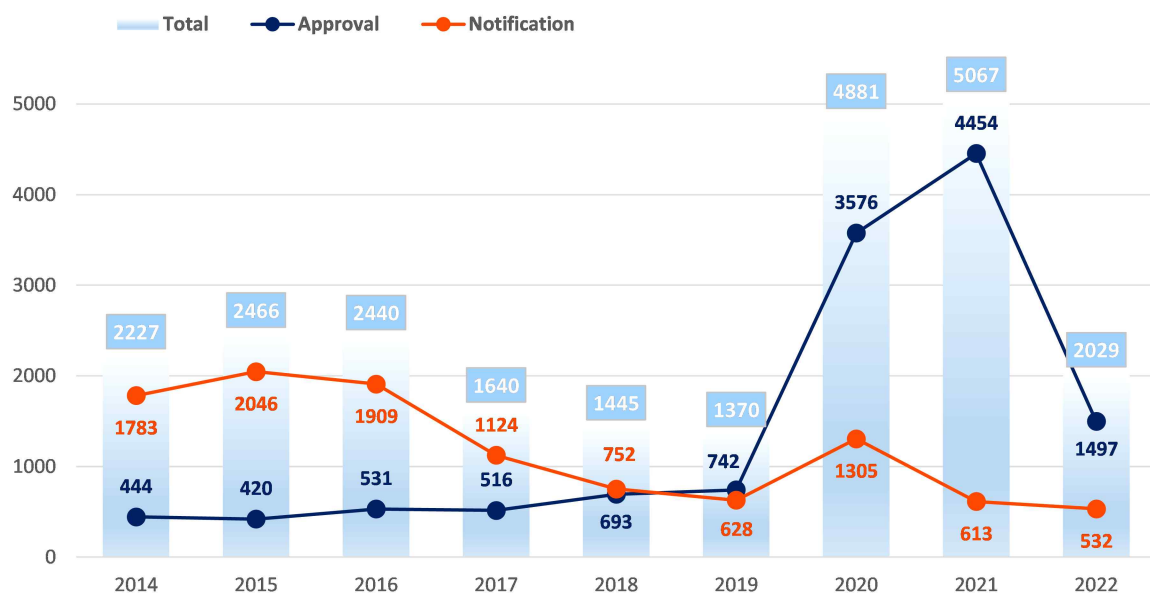


Fig. 1 Manufacturing(Import) Approval and Notification Status by Year
(number of items, 2014~2022)

When 2022 status was identified in terms of manufacturing and import, 1,431 items(73.9%) in manufacturing were for approval, and 66 items(71.7%) in import were for approval, showing that approval accounted for the most part.

Table 3 Approval and Notification Status by Manufacturing and Import in 2022

(Unit: Number of Items)

Classification	Total	Manufacturing	Import
Approval	1,497	1,431 (73.9%)	66 (71.7%)
Notification	532	506 (26.1%)	26 (28.3%)
Total	2,029	1,937 (100%)	92 (100%)

When 2022 status was classified by processing institution(head office, regional office), 1,465 items(97.9%) were handled by regional offices out of 1,497 items for approval.

Table 4 Approval and Notification Status by Processing Institution in 2022

(Unit: Number of Items)

Classification	Total	Head office	Regional office
Approval	1,497	32 (2.1%)	1,465 (97.9%)
Notification	532	—	532
Total	2,029	32 (1.6%)	1,997 (98.4%)

When analyzing the handling status of regional offices in 2022, 1,911 items (95.7%) were for approval and 86 items(4.3%) were for notification out of a total of 1,997 items.

Among manufacturing items, 1,431 items (73.9%) were for approval. Among import items, 66 items(71.7%) were for approval, showing higher rate than the items for notification.

Table 5 Manufacturing(Import) Approval and Notification Status by Processing Institution in 2022

(Unit: Number of Items)

Manufacturing (1,937 items)		Import (92 items)	
Approval (1,431)	Head office (26)	Approval (66)	Head office (6)
	Regional office (1,405)		Regional office (60)
Notification (506)	Regional office (506)	Notification (26)	Regional office (26)

When classifying the regional office status by 6 regional offices, Gyeongin Office processed the most with 840 items(42.1%), followed by Seoul office with 351 items(17.6%). 1,191 items of 2 local offices were found to account for 59.7% of total processing status.

Table 6 Manufacturing(Import) Approval and Notification Status by Regional Office in 2022

(Unit: Number of Items)

Classification		Approval	Notification	Total
Regional Office	Gyeongin office	676 (46.1%)	164 (30.8%)	840 (42.1%)
	Seoul office	251 (17.1%)	100 (18.8%)	351 (17.6%)
	Daejeon office	207 (14.1%)	165 (31.0%)	372 (18.6%)
	Daegu office	130 (8.9%)	40 (7.5%)	170 (8.5%)
	Busan office	122 (8.3%)	47 (8.8%)	169 (8.5%)
	Gwangju office	79 (5.4%)	16 (3.0%)	95 (4.8%)
Total		1,465 (73.4%)	532 (26.6%)	1,997 (100.0%)

1.2. Manufacturing(Import) Approval and Notification Status by Classification Number

When examining the approval and notification status in 2022 by classification number, filtering respirator(53.5%), menstrual pad(16.6%), anti-droplet mask(11.5%) take 81.6%. Besides, toothpaste, adhesive bandage, external disinfectant, surgical mask, mouthwash were found to be subject to approval and notification.

Table 7 Approval and Notification Status by Classification Number in 2022

(Unit: Number of Items)

Code Total	Filtering Respirator [3220]	Menstrual Pad [3110]	Anti-droplet Mask [3230]	Toothpaste [4140]	bAdhesive Bandage [3380]	External Disinfectant [4600]	Surgical Mask [3210]	Mouthwash [4110]	Others
2,029	1,086 (53.5%)	336 (16.6%)	233 (11.5%)	122 (6.0%)	110 (5.4%)	55 (2.7%)	18 (0.9%)	16 (0.8%)	53 (2.6%)

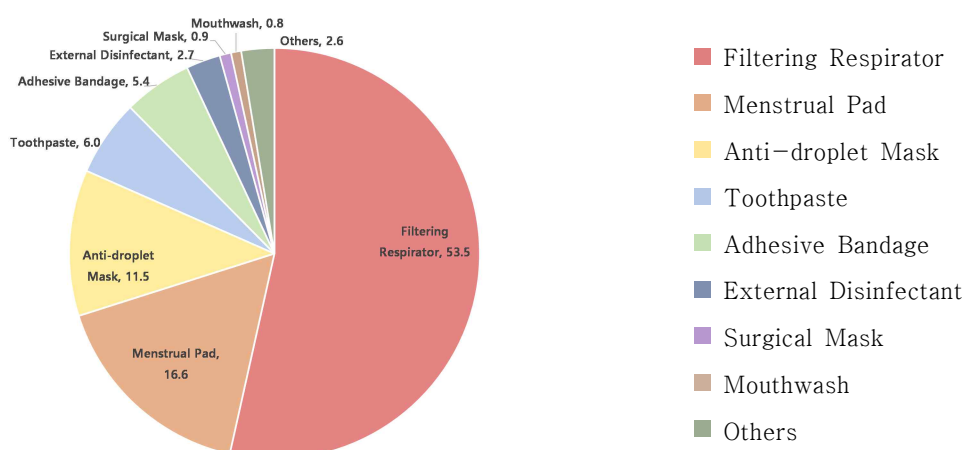


Fig. 2 Approval and Notification Distribution by Classification Number in 2022

When comparing approval and notification status by classification number in 2022 with that of 2021, filtering respirator accounted for the highest rate at 53.5%(1,086 items) for 2 consecutive years, while 3 types of quasi-drug mask(filtering respirator, anti-droplet mask, surgical mask) approval and notification were 1,337 items, accounting for 65.9% of total in 2022.

However, when comparing the approval and notification status by classification number with that of 2021, the overall number of items decreased. In particular, the number of anti-droplet mask was 233 items in 2022, a decrease of 72.4% compared to 2021 (1,076 items), showing the highest decrease rate.

Table 8 Approval and Notification Status by Classification Number in 2022 (2021~2022)

(Unit: Number of Items)

Year	Filtering Respirator [3220]	Menstrual Pad [3110]	Anti-droplet Mask [3230]	Toothpaste [4140]	Adhesive Bandage [3380]	External Disinfectant [4600]	Surgical Mask [3210]	Mouth Freshener [4110]	Others	Total
'22	1,086 (53.5%)	336 (16.6%)	233 (11.5%)	122 (6.0%)	110 (5.4%)	55 (2.7%)	18 (0.9%)	16 (0.8%)	53 (2.6%)	2,029
'21	2,819 (55.6%)	392 (7.7%)	1,076 (21.2%)	128 (2.5%)	188 (3.7%)	147 (2.9%)	232 (4.6%)	19 (0.4%)	66 (1.3%)	5,067

Table 9 Detailed Status of Approval and Notification by Classification Number in 2022

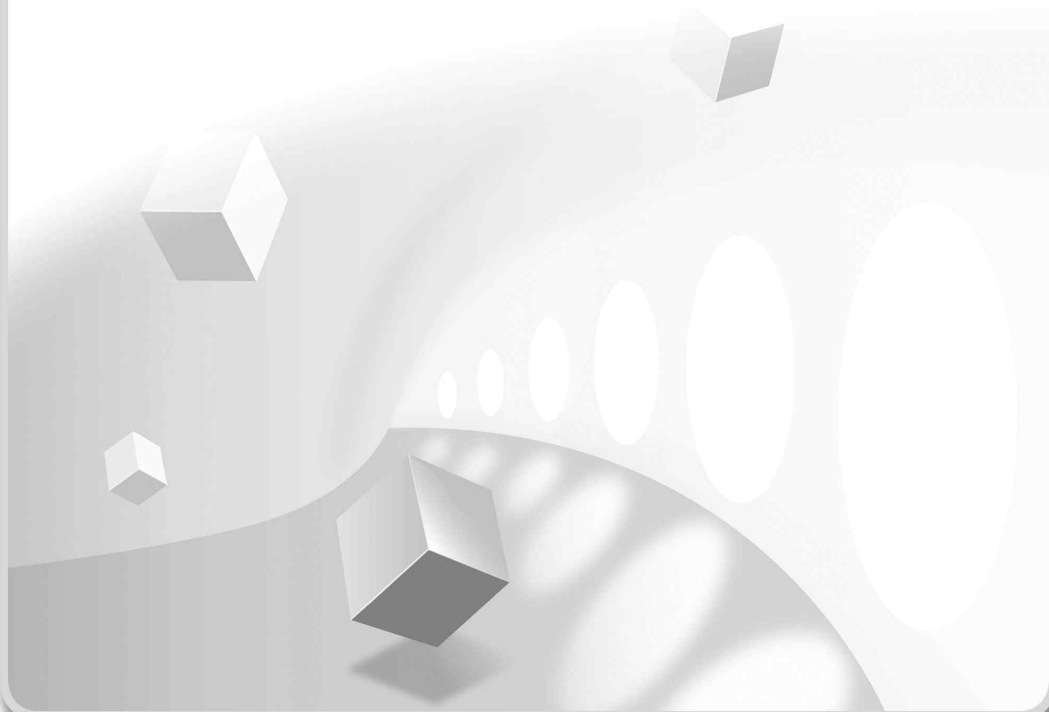
Classification	Classification Number		Number of items
Article A*	3110	Menstrual Pad	336
	3120	Menstrual Tampon	6
	3130	Menstrual Cup	3
	3210	Surgical Mask	18
	3220	Filtering Respirator	1,086
	3230	Anti–droplet Mask	233
	3310	Eye Bandage	–
	3320	Bandage	1
	3330	Elastic Bandage	1
	3360	Gauze	3
	3370	Absorbent Cotton	4
	3380	Adhesive Bandage	110
	Subtotal		1,801
Article B**	4110	Mouth Freshener(Internal formulation and mouthwash)	16
	4130	Heat Rash–sores Treatment Product	2
	4140	Toothpaste	122
	4320	Repellent	6
	4400	Contact Lens Care Product	5
	4600	External Disinfectant	55
	4711	Ointment	1
	4713	Spray Patch	2
	4721	Low–content Vitamin and Mineral Agent	3
	4722	Nutrients, Tonic and Alternatives (Internal liquid formulation only)	1
	4723	Stomach Digestive Medicine (Internal liquid formulation only)	1
	4840	Teeth Whitener	4
	4850	Detergent for the purpose of cleaning and disinfecting the items detachable and used in the oral capacity including dentures and braces	–
	Subtotal		218
Items similar to Article A and Article B	3500	Other Similar Product	7
	4920	Air composition or oxygen–containing portable product intended for human inhalation	3
	Subtotal		10
Total			2,029

* Items falling on Article A of Clause 7 of Article 2 of Pharmaceutical Affairs Act

** Items falling on Article B of Clause 7 of Article 2 of Pharmaceutical Affairs Act

2

Detailed Status of Quasi-Drug Approval in 2022



2. Detailed Status of Quasi-Drug Approval in 2022 •

Quasi-Drug is classified into Article A or Article B according to Clause 7, Article 2 of the Pharmaceutical Affairs Act (hereunder Article A or Article B Quasi-Drug); and items subject to safety and efficacy examination and items not subject to such examination depending on the type of examination.

Among 1,497 items for approval in 2022, quasi-drug under Article A were 1,437 items(96.0%), quasi-drug under Article B were 51 items(3.4%), and quasi-drug similar to Article A and Article B were 9 items(0.6%). That is, quasi-drug under Article A take most of items and it was similar percentage compared to 2021.

Among the quasi-drugs approved in 2022, 32 items were subject to safety and efficacy examination. Among them, 26 items(81.3%) were in manufacturing; while 6 items(18.8%) were import, which is increase of 12 items(60.0%), compared to 20 items in 2021.

When analyzing the 32 items approved in 2022, subject to safety and efficacy examination, 17 items of quasi-drug(menstrual pad 10 items, filtering respirator 3 items, anti-droplet mask 4 items) are in Article A 13 items of quasi-drug are in Article B (mouth freshener 3 items, toothpaste 7 items, repellent 2 items, external disinfectant 1 item), 2 items are in items similar to Article A and Article B(2 items of air composition, manufactured for human inhalation).

Table 10-1 Approval Status by Article of Quasi-Drugs(2021~2022)

(Unit: number of items)

Year	Total	Article A	Article B	Article C*	Article A and Article B similar
'22	1,497	1,437 (96.0%)	51 (3.4%)	—	9 (0.6%)
'21	4,454	4,367 (98.0%)	79 (1.8%)	—	8 (0.2%)

* Pesticides for quarantines in Item C and Article B of Clause 7, Article 2 of Pharmaceutical Affairs Act are transferred to the Ministry of Environment on Jan. 1, 2019

Table 10-2 Status of Approval Subject to Manufacturing and Import Safety and Efficacy Examination (2021~2022)

(Unit: Number of Items)

Year	Total	Manufacturing	Import
'22	32	26(81.3%)	6(18.8%)
'21	20	15(75.0%)	5(25.0%)

Table 10-3 Status of Approval Subject to Safety and Efficacy Examination by Article in 2022

	Type	Item Classification	Number of items approved
1	Article A Quasi-drug	Menstrual Pad	10
		Filtering Respirator	3
		Anti-droplet mask	4
2	Article B Quasi-drug	Mouth Freshener (Internal formulation and mouthwash)	3
		Toothpaste	7
		Repellent	2
		External Disinfectant	1
3	Quasi-Drug similar to Article A and Article B	Air composition or oxygen-containing portable product intended for human inhalation	2

2.1. Article A Quasi-Drug Approval Status

Article A quasi-drug are the products that fail on ‘Fibers, rubber products or similar products used for the purpose of treating, alleviating, or preventing human or animal diseases’, including menstrual pad, mask and gauze.

In terms of Article A quasi-drug approval status in 2022, filtering respirator recorded the most with 1,025 items(71.3%), followed by 222 items(15.5%) of anti-droplet mask and 115 items(8.0%) of menstrual pad and 52 items(3.6%) of adhesive bandage.

Table 11 Approval Status of Article A Quasi-Drug in 2022

By item		Approval (number)
Menstrual Hygiene Management Product	Menstrual pad	115
	Menstrual Cup	3
Mask	Surgical Mask	17
	Filtering Respirator	1,025
	Anti–droplet Mask	222
Product used for preservation, protection and treatment of the affected areas	Elastic Bandage	1
	Gauze	2
	Adhesive Bandage	52
Total		1,437

1) Mask

With regard to quasi-drug mask, there are a total of 3 types with additional designation of anti-droplet mask in June 2020. In 2022, 1,264 items(17 items of surgical mask, 1,025 items of filtering respirator 1,025 and 222 items of anti-droplet mask) were approved.

Among the items approved in 2022, 7 items (3 items of filtering respirator, 4 items of anti-droplet mask) were subject to safety and efficacy examination, corresponding to new materials(6 items) or new usages(1 item). Masks in a form different from existing one, such as anti-droplet mask with transparent window that allows to check the shape of a person's mouth as well as filtering respirator without filtering respirator without nose wire were approved after safety and efficacy examination.

Table 12 Status of Approval Subject to Mask Safety and Efficacy Examination in 2022

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	와이어리스방역보건용 마스크(KF94)(대형)(흰색)	친환경대한민국 주식회사	2022-03-21	[32200] filtering respirator	New usage
2	Mfg.	더조은투명창비말차단 마스크(KF-AD)(대형)	더조은주식회사	2022-04-05	[32300] anti-droplet mask	New materials
3	Mfg.	1.더조은투명창비말차단 마스크(KF-AD)(중형), 2.더조은투명창비말차단 마스크(KF-AD)(소형)	더조은주식회사	2022-04-05	[32300] anti-droplet mask	New materials
4	Mfg.	케이엠클린네오케어비말 차단마스크(KF-AD)	(주)케이엠	2022-07-06	[32300] anti-droplet mask	New materials

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
5	Mfg.	케이엠클린네오케어비말 차단입체마스크(KF-AD)	(주)케이엠	2022-07-07	[32300] anti-droplet mask	New materials
6	Mfg.	르마스카솔리드마스크 (KF80)(대형)	주식회사르마스카	2022-07-12	[32200] filtering respirator	New materials
7	Mfg.	에어워셔에코그린항사 방역용마스크(KF94)(대형)	(주)엘지생활건강	2022-12-05	[32200] filtering respirator	New materials

* Approved information of each products(efficacy/effectiveness, direction for use, dosage and cautions for use) can be checked at website(<http://nedrug.mfds.go.kr>)

2) Menstrual Hygiene Management Product

Menstrual Hygiene Management Product includes menstrual pads, menstrual tampon and menstrual cup. In 2022, 118 items(115 items of sanitary pads, 3 items of menstrual cups) were approved.

Among the items approved in 2022, 10 items of menstrual pads were subject to safety and efficacy examination, which corresponded to new materials (9 items) or new efficacy (1 item).

Table 13 Status of Approval Subject to Menstrual Hygiene Management Product Safety and Efficacy Examination in 2022

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	화이트수퍼흡수중형비	유한킴벌리(주)	2022-06-02	[31100] menstrual pad	New materials
2	Mfg.	화이트네이처울트라슬림 대형비	유한킴벌리(주)	2022-06-02	[31100] menstrual pad	New materials
3	Mfg.	좋은느낌유울트라슬림 대형비	유한킴벌리(주)	2022-06-07	[31100] menstrual pad	New materials
4	Mfg.	라네이처시그니처울트라 슬림대형비	유한킴벌리(주)	2022-06-07	[31100] menstrual pad	New materials
5	Import	청담소녀입는오버나이트 슬림	주식회사 한컴헬스케어	2022-07-20	[31100] menstrual pad	New efficacy
6	Mfg.	좋은느낌울트라날개대형 케이	유한킴벌리(주)	2022-07-22	[31100] menstrual pad	New materials
7	Mfg.	좋은느낌좋은순면울트라 중형케이	유한킴벌리(주)	2022-07-22	[31100] menstrual pad	New materials
8	Mfg.	좋은느낌울트라날개대형 케이	유한킴벌리(주)	2022-07-25	[31100] menstrual pad	New materials
9	Mfg.	내추럴프랜드생리대중형	(주)에스에스케이	2022-10-07	[31100] menstrual pad	New materials

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
10	Mfg.	1.레브소미프리미엄면 생리대소형, 2.레브소미 프리미엄면생리대중형, 3.레브소미프리미엄면 생리대대형, 4.레브소미 프리미엄면생리대특대형	주식회사 대양바이오랩	2022-11-15	[31100] menstrual pad	New materials

* Approved information of each products(efficacy, effect, direction for use, dosage and cautions for use) can be checked at website(<http://nedrug.mfds.go.kr>)

2.2. Article B Quasi-Drug Approval Status

Article B quasi-drug are the products that correspond to 'Non-appliance, non-machinery or similar articles that have insignificant influences on or do not directly act upon human bodies', including mouth freshener(internal formulation and mouthwash), toothpaste or external disinfectant, etc.

In terms of Article B quasi-drug approval status in 2022, toothpaste recorded the most with 24 items(47.1%), followed by 11 items (21.6%) of mouth freshener and 10 items(19.6%) of external disinfectant.

Table 14 Article B Quasi-Drug Approval Status in 2022

By item		Approval (number)
Preventive Oral Care Product	Mouth Freshener(Internal formulation and mouthwash)	11
	Heat Rash-sores Treatment Product	2
	Toothpaste	24
External Disinfectant		10
Teeth Whitener		2
Repellent		2
Total		51

1) Preventive Oral Care Product

Preventive oral care product include mouth freshener, heat rash-sores treatment product and toothpaste. In 2022, 37 items(11 items of mouth freshener, 2 items of heat rash-sores treatment product, 24 items of toothpastes) were approved.

Among the items approved in 2022, 10 items(3 items of mouth freshener, 7 items of toothpaste) were subject to safety and efficacy examination.

Items subject to safety and efficacy examination among the preventive oral care product in 2022 are classified into content increase and decrease combination drug(5 items), combination with new composition(2 items), single agent(1 item), new efficacy and effect (1 item) and formulations containing new substance(1 item).

Table 15 Status of Approval Subject to Preventive Oral Care Product Safety and Efficacy Examination in 2022

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	동의본초마우스워시액	(주)아모레퍼시픽	2022-04-05	[41100] mouth freshener	Complex with new composition
2	Mfg.	페리오에이치아이 화이트치약	(주)엘지생활건강	2022-04-18	[41400] toothpaste	Complex with contents increase and decrease
3	Import	네네텐트어린이치약 (딸기향)	한국연료전지 주식회사	2022-04-28	[41400] toothpaste	Complex with contents increase and decrease

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
4	Import	센소다인리페어애프로 텍트치약	(주)글락소스미스 클라인컨슈머헬스 케어코리아	2022-05-24	[41400] toothpaste	Complex with new composition
5	Import	글리스터컴플리트컨센 트레이티드마우스워시 액(세틸피리디늄염화 물)	한국암웨이(주)	2022-07-12	[41100] mouth freshener	Single agent
6	Mfg.	젠티스트투엑스쿨민트 치약	(주)아모레퍼시픽	2022-07-29	[41400] toothpaste	Complex with contents increase and decrease
7	Import	1.큐라프록스치약 (민트향), 2.큐라프록스치약 (수박향)	코스메디칼솔루션 리서치	2022-08-12	[41400] toothpaste	Complex with contents increase and decrease
8	Mfg.	화이트닝에센셜스 오리지널	(주)엘지생활건강	2022-09-08	[41400] toothpaste	Agent containing new substance
9	Import	1.콜게이트후레쉬티 마우스워시, 2.콜게이트아이스민트 마우스워시	(주)우삼코리아	2022-09-26	[41100] mouth freshener	New efficacy/effe ct
10	Mfg.	콜마에스알치약	한국콜마(주)	2022-12-06	[41400] toothpaste	Complex with contents increase and decrease

* Approved information of each products(efficacy, effect, direction for use, dosage and cautions for use) can be checked at website(<http://nedrug.mfds.go.kr>)

2) External Disinfectant

Products with main components of hydrogen peroxide, isopropyl alcohol, benzalkonium chloride, cresol or ethanol directly used on human body are designated as external disinfectants, and 10 items were approved in 2022.

Among the items approved in 2022, 1 item was subject to safety and efficacy examination.

Table 16 Status of Approval Subject to External Disinfectant Safety and Efficacy Examination in 2022

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	핸드케어안심손소독제 겔 75%(에탄올)	(주)리베코스	2022-10-18	[46000] external disinfectant	—

* Approved information of each products(efficacy, effect, direction for use, dosage and cautions for use) can be checked at website(<http://nedrug.mfds.go.kr>)

2.3. Approval Status of Quasi-Drugs Similar to Article A and Article B

Quasi-Drug similar to Article A or Article B are the products that fall on No. 4 of 「Designation of Scope of Quasi-Drug」 (Notice of Ministry of Food and Drug Safety), including ▲non-adhesive goods used for absorbing the exudate, etc. from the affected area ▲sterilized goods used during surgical procedure for prevention of infection ▲wet tissue for oral cleaning ▲products used to temporarily adjust the color of teeth by applying to the surface of teeth ▲portable products used for human inhalation with temporary supply of air or oxygen before or after mountain climbing or exercise ▲products used for sanitary treatment of bleeding or oro (postpartum vaginal secretions) immediately after childbirth(generally called ‘mother pad’) and ▲products similar to Item A, Clause 7 of Article 2 of 「Pharmaceutical Affairs Act」.

9 items were approved including non-adhesive goods (6 items) and portable items (3 items) were approved as the quasi-drug similar to Article A and Article B in 2022, and 2 items were subject to safety and efficacy examination among the approved items.

Table 17 Status of Approval of Quasi-Drug Similar to Article A and Article B in 2022

By item	Approval (number)
Non-adhesive products used for absorbing exudate from the affected area	6
Air composition or oxygen-containing portable product intended for human inhalation	3
Total	9

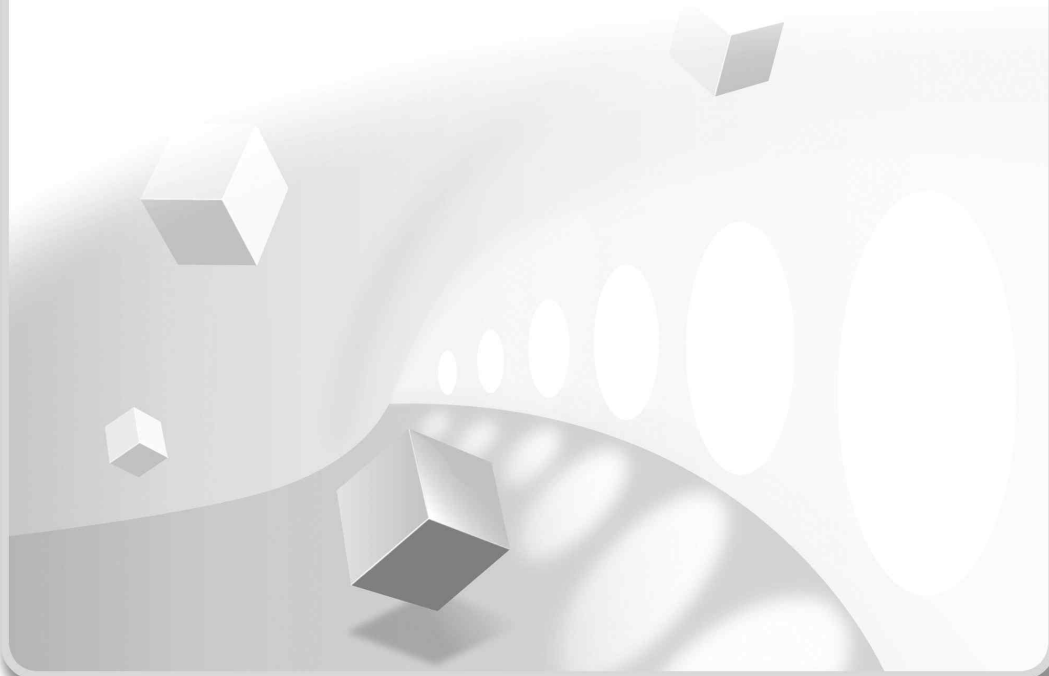
Table 18 Approval Status of Items Subject to Portable Product Safety and Efficacy Examination in 2022

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	힐링휴대용에어	평창에어(주)	2022-02-11	[49200] air composition or oxygen-containing portable product intended for human inhalation	Air composition
2	Mfg.	지리청정휴대용에어	주식회사 지리에어	2022-08-29	[49200] air composition or oxygen-containing portable product intended for human inhalation	Air composition

* Approved information of each products(efficacy, effect, direction for use, dosage and cautions for use) can be checked at website(<http://nedrug.mfds.go.kr>)

3

Quasi-Drug Approval Trend



3. Quasi-Drug Approval Trend



3.1. Quasi-Drug Approval Management Status

Expansion of the scope of quasi-drug has been continuously pursued to preemptively secure safety of consumers.

In 2019, ‘products used for sanitary treatment of bleeding or oro (postpartum vaginal secretions) immediately after childbirth was additionally designated as quasi-drug, and 2 items have been approved up to now since the effective date(Oct. 1, 2021).

In 2020, anti-droplet mask was newly designated as a quasi-drug(June 1, 2020) to prevent infectious disease and to block transmission of disease in Covid 19 pandemic situations. A standard specification was prepared for the raw materials used in the mask (plastic nose wire, ear loops) and added to the standard and test methods for quasi-drug(Feb. 26, 2021).

In 2021, quasi-drug was added to the list of electronic permit issuance and management to improve work efficiency and convenience of quasi-drug permit application and processing as well as to reduce the issuance and use of paper documents such as permit in preparation for the era of carbon neutrality

In 2022, the item notification procedure of quasi-drug mask was prepared by standardizing the quasi-drug mask standards which rapidly increased in marketing approval since spread of COVID 19 and creating the standard specifications for filtering respirator(KF94, KF80),

anti-droplet mask and surgical mask, along with standard specifications for reinforcing the management of non-woven fabrics or cotton non-woven fabrics for mask.

It is planned to continue to support product development through creation of new standardized quasi-drug standard specification and improvement of approval management system.

3.2. Quasi-Drug Approval Trend and New Quasi-Drug Approval Status in 2022

Until 2019, menstrual pad had accounted for a large portion, which had increased convenience according to various kinds of lifestyle patterns of consumers, but since 2020, masks, used as personal quarantine items, have been at the top position due to influence of Covid 19 pandemic.

In 2020, new approval of masks(surgical mask, filtering respirator, anti-droplet mask) and external disinfectant rapidly increased and recorded 3,325 items, accounting for 93% of total 3,576 items approved.

In 2021, as COVID 19 continued, new approvals of masks, the essential quarantine items, recorded 4,127 items, an increase of 802 items in 2020, taking 81.4% of total 5,067 items approved.

In 2022, the number of new items of relevant products significantly decreased compared to 2021, due to stabilization of supply of quarantine products to markets as well as easing of mandatory outdoor mask wearing. In particular, anti-droplet mask decreased by 843 items compared to 2021, recording highest decrease(72.4%).

Table 19 Status of Top 5 Items(classification number) Approved by Year(2019~2022)

	2019		2020		2021		2022	
	Item (classification number)	Number of items	Item (classification number)	Number of items	Item (classification number)	Number of items	Item (classification number)	Number of items
1	Menstrual Pad (3110)	491 (35.8%)	Filtering Respirator (3220)	1,651 (46.2%)	Filtering Respirator (3220)	2,819 (63.3%)	Filtering Respirator (3220)	1,025 (68.5%)
2	Filtering Respirator (3220)	439 (32.0%)	Anti-droplet Mask (3230)* (3230)	1,214 (33.9%)	Anti-droplet Mask (3230)	1,076 (24.2%)	Anti-droplet Mask (3230)	222 (14.8%)
3	Toothpaste (4140)	152 (11.1%)	Surgical mask (3210)	408 (11.4%)	Menstrual Pad (3110)	149 (3.3%)	Menstrual Pad (3110)	115 (7.7%)
4	Adhesive Bandage (3380)	105 (7.7%)	Menstrual Pad (3110)	114 (3.2%)	Surgical mask (3210)	232 (5.2%)	Adhesive Bandage (3380)	52 (3.5%)
5	External Disinfectant (4600)	26 (1.9%)	External Disinfectant (4600)	52 (1.5%)	Adhesive Bandage (3380)	78 (1.8%)	Toothpaste (4140)	24 (1.6%)
Approval (number)		1,370 (100%)		3,576 (100%)		4,454 (100%)		1,497 (100%)

* Additionally designated as a quasi-drug on June 1, 2020

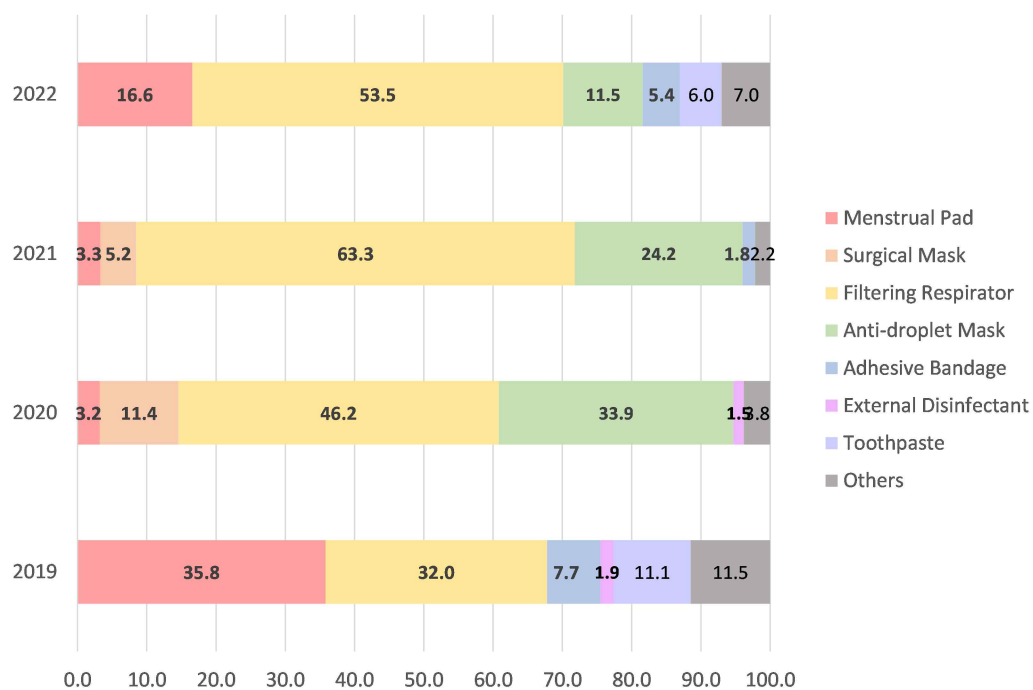
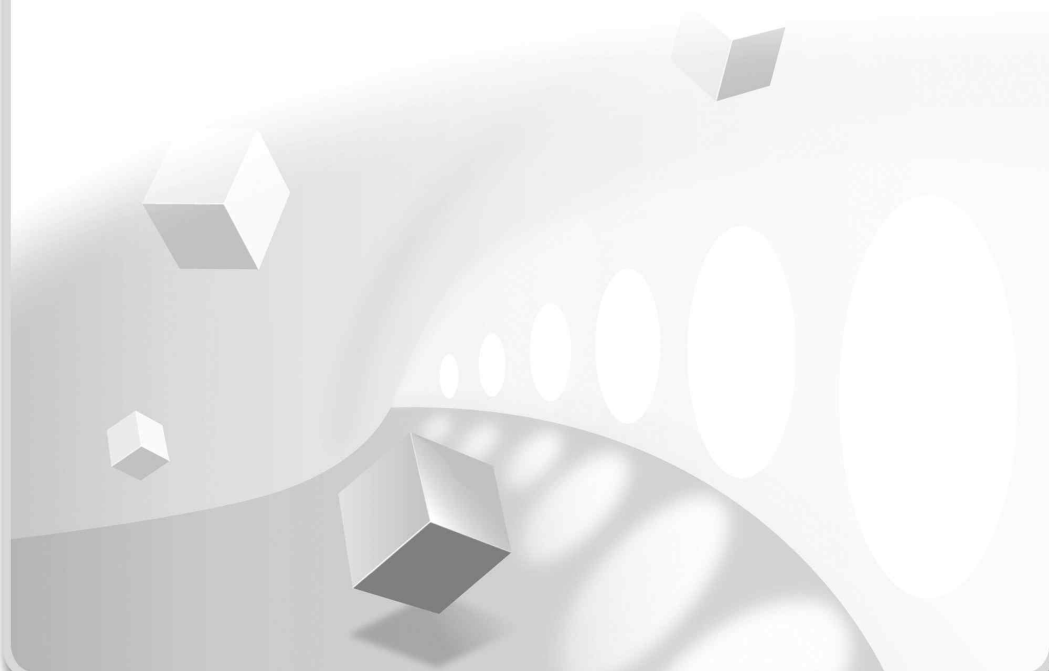


Fig. 3 Percentage of Approval by Year and Quasi-Drug Classification Number (2019~2022)

4

Appendix



Appendix I Overview of Quasi-Drug Approval and Notification

Quasi-drugs are defined under subparagraph 7, Article 2 of the Pharmaceutical Affairs Act and classified into 3 categories. The Minister of Food and Drug Safety designates and announces the scope of such items accordingly.

< Pharmaceutical Affairs Act> Subparagraph 7, Article 2

7. The term “quasi-drug” means any of the following articles designated by the Minister of Food and Drug Safety (excluding articles which shall be used for the purposes described in subparagraph 4 (b) or (c)):
- (a) Fibers, rubber products, or similar products used for the purpose of treatment, alleviation, care, or prevention of human or animal diseases;
 - (b) Non-appliance, non-machinery or similar articles that have insignificant influences on or do not directly act upon human bodies;
 - (c) Medication for sterilization, insecticide, and other similar uses for the purpose of preventing infectious diseases;

For application of products as quasi-drug, the products should be subject to marketing approval or notification based on the need for safety and effectiveness examination or availability of process procedures for the products. An item that falls under any of the following categories should be subject to marketing notification:

- Items which are listed in the 「Korean Pharmacopoeia」 or the procedure or formulary accepted by the Minister of Food and Drug Safety, excluding those not approved in Korea
- Items of which the standards and test methods are announced by

the Minister of Food and Drug Safety

- Items which meet the standard manufacturing criteria announced by the Minister of Food and Drug Safety.

Appendix II

Departments in Charge of Civil Petition Regarding Quasi-Drug

Table 20 Status of Departments Related to Quasi-Drug (as of Apr. 2023)

Classification	Department	Detailed Petition Service
Director for Novel Products Approval		Quasi-drug manufacturing(import) approval (including change) • Items subject to safety and effectiveness examination only
Biopharmaceuticals and Herbal Medicine Bureau	Quasi-drugs Policy Division	Quasi-drug GMP evaluation
National institute of Food and Drug Safety Evaluation	Biopharmaceuticals and Herbal Medicine Evaluation Dept. Cosmetics Evaluation Division	Quasi-drug • Safety and effectiveness examination • Review of quality data • Preview
Seoul Regional Office of Food and Drug Safety	Pharmaceutical Safety Management Division	Quasi-drug manufacturing(import) approval and notification (including change) • Limited to items not subject to safety and effectiveness examination
Gyeongin Regional Office of Food and Drug Safety	Medical Products Safety Division	
Daejeon Regional Office of Food and Drug Safety		
Busan Regional Office of Food and Drug Safety		
Daegu Regional Office of Food and Drug Safety		
Gwangju Regional Office of Food and Drug Safety		

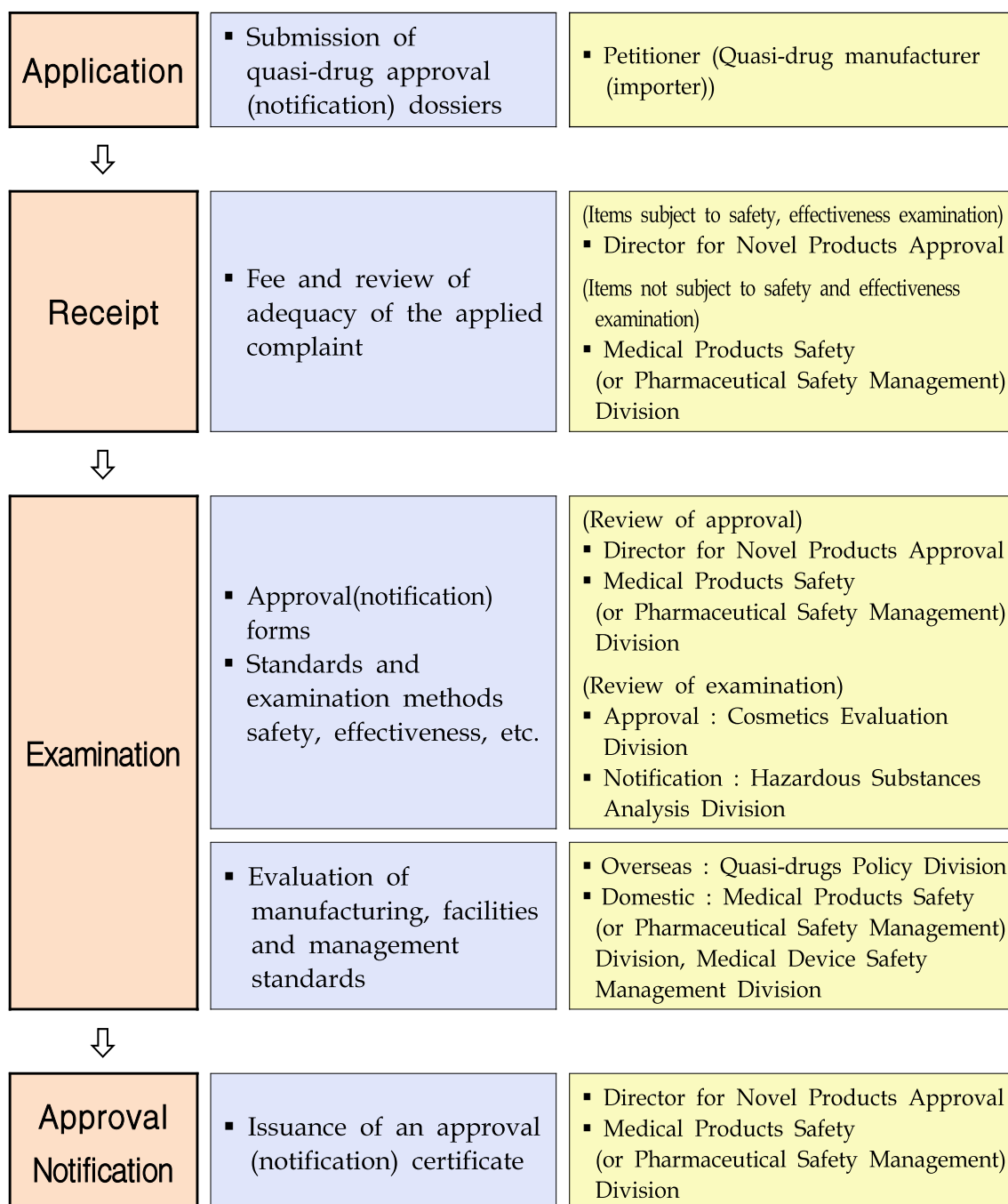


Fig. 4 Quasi-Drug Manufacturing(Import) Approval and Notification Procedure

Appendix IV Quasi-Drug Approval and Notification Status

Table 21 Quasi-Drug Manufacturing(Import) Approval and Notification Status by Year ('19~'22)
(Unit: Number of Items)

Year	Total	Approval	Notification	Head office	Regional Office	Mfg.	Inport
'22	2,029	1,497 (73.8%)	532 (26.2%)	32 (1.6%)	1,997 (98.4%)	1,937 (95.5%)	92 (4.5%)
'21	5,067	4,454 (87.9%)	613 (12.1%)	20 (0.4%)	5,047 (99.6%)	4,881 (96.3%)	186 (3.7%)
'20	4,881	3,576 (73.3%)	1,305 (26.7%)	53 (1.1%)	4,828 (98.9%)	4,613 (94.5%)	268 (5.5%)
'19	1,370	742 (54.2%)	628 (45.8%)	28 (2.0%)	1,342 (98.0%)	1,178 (86.0%)	192 (14.0%)

* Including cancellation or withdrawal, excluding for export

Table 22 Approval and Notification Status by Classification Number ('19~'22)
(Unit: Number of Items)

Year	Filtering Respirator [3220]	Menstrual Pad [3110]	Anti-droplet Mask [3230]	Toothpaste [4140]	Adhesive Bandage [3380]	External Disinfectant [4600]	Surgical Mask [3210]	Mouthwash [4110]	Others	Total
'22	1,086 (53.5%)	336 (16.6%)	233 (11.5%)	122 (6.0%)	110 (5.4%)	55 (2.7%)	18 (0.9%)	16 (0.8%)	13 (2.6%)	2,029
'21	2,819 (55.6%)	392 (7.7%)	1,076 (21.2%)	128 (2.5%)	188 (3.7%)	147 (2.9%)	232 (4.6%)	19 (0.4%)	66 (1.3%)	5,067
'20	1,651 (33.8%)	436 (8.9%)	1,214 (24.9%)	204 (4.2%)	128 (2.6%)	755 (15.5%)	408 (8.4%)	17 (0.3%)	68 (1.4%)	4,881
'19	439 (32.0%)	491 (35.8%)	—	152 (11.1%)	105 (7.7%)	26 (1.9%)	22 (1.6%)	12 (0.9%)	58 (4.2%)	1,370

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