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Quasi-Drug Approval Report

Jun. 2025.



**Ministry of Food and
Drug Safety**

**Biopharmaceuticals and Herbal Medicine Bureau
Biopharmaceutical Approval TF**

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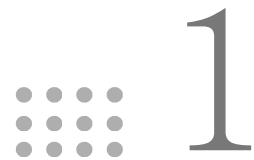
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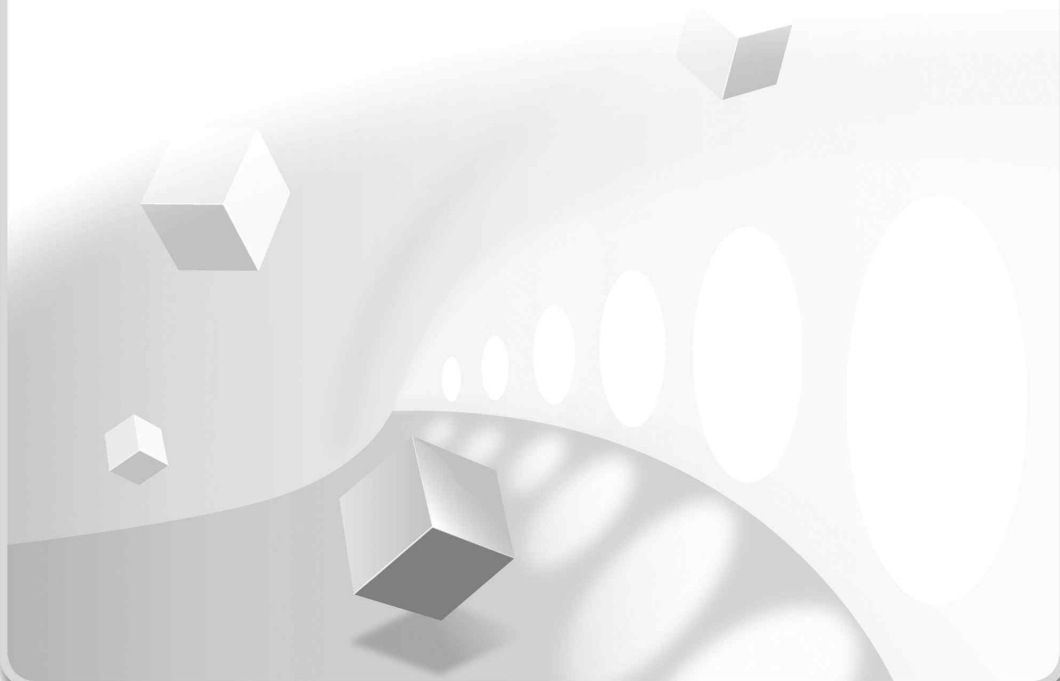
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General Status of Quasi-Drug Approval (Notification) in 2024



1. General Status of Quasi-Drug Approval (Notification) in 2024

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 or import approval and notification status.

There are a total of 659 items in quasi-drug manufacturing or import approval and notification in 2023, which is 270 item(29.1%) decrease from 929 items in 2023.

Among them, there are 567 items(86.0%) in manufacturing and 92 items(14.0%) in import, which means that domestic manufacturing items are more than 6 times that of import items. There are 463 items(70.3%) in approval and 196 items(29.7%) in notification, which means that the number of approval items is about twice that of notification items.

By institution, 36 items (5.5%) were handled by head office, 623 items (94.5%) by local office. As a result of analyzing the items processed by the regional office, there were 427 items(68.5%) for approval and 196 items(31.5%) for notification

1.1. General Status

There are a total of 659 items in quasi-drug manufacturing and import approval and notification in 2024. Compared to those in 2023, there were 149 items (-24.3%) in total approval, meaning 190 item(-23.3%) decrease in approval and notification to regional office, and 294 item(-34.1%) decrease in manufacturing, and notification items have shown a continuous decreasing trend since 2015.

When comparing the status of 2024 in terms of domestic manufacturing and import, most of them corresponded to domestic manufacturing (86.0%), similar to 2023, and the proportion of import slightly increased compared to the previous year.

Table 1 Quasi-Drug Manufacturing and Import Approval/ Notification Status('23~'24)

(Unit : Number of Items)

Year	Total	Approval	Notification	Mfg.	Import	Head Office	Regional Office
'24	659	463 (70.3%)	196 (29.7%)	567 (86.0%)	92 (14.0%)	36 (5.5%)	623 (94.5%)
'23	929	612 (65.9%)	317 (34.1%)	861 (92.7%)	68 (7.3%)	116 (12.5%)	813 (87.5%)

* Including cancellation or withdrawal, excluding for export

Table 2 Manufacturing and Import Approval and Notification Status by Year

(Unit : Number of Items)

Classification	2016	2017	2018	2019	2020	2021	2022	2023	2024
Approval	531	516	693	742	3,576	4,454	1,497	612	463 (70.3%)
(Year-on-year increase %)	-2.8	34.3	7.1	381.9	24.6	-66.4	-59.1		-24.3
Notification	1,909	1,124	752	628	1,305	613	532	317	196 (29.7%)
(Year-on-year increase %)	-41.1	-33.1	-16.5	107.8	-53.0	-13.2	-40.4		-38.2
Total	2,440	1,640	1,445	1,370	4,881	5,067	2,029	929	659
(Year-on-year increase %)	-32.8	-11.9	-5.2	256.3	3.8	-60.0	-54.2		-29.1

When comparing the number of manufacturing and import approval and notification items by year for recent 10 years, it maintained about 2,400 items in '15~'16 while it temporarily decreased to 1,500 items in '17~'19 due to transfer of 4 item groups (hair loss agents, hair dyes, hair removal products and bath products), which had occupied high proportion in notification items according to the revision of 「Cosmetics Act」 (May 30, 2017), to functional cosmetics.

While the number of items in approval and notification rapidly increased to about 5,000 items in '20~'21, due to significant increase in national demands for personal disinfection such as masks and external disinfectants, following outbreak of Covid 19 pandemic, the approval and notification items in 2022 were about 2,000, returning to the pre-Covid 19 level due to stabilization of supply and demand of disinfection products as well as phased easing of mandatory mask wearing.

The total number of approval and notification items was 929 items in 2023 and continued to decrease overall compared to the previous year, reaching 659 items in 2024(-29.1% from 2023) as the downward trend in approval and notification of quarantine supplies continued since 2022.

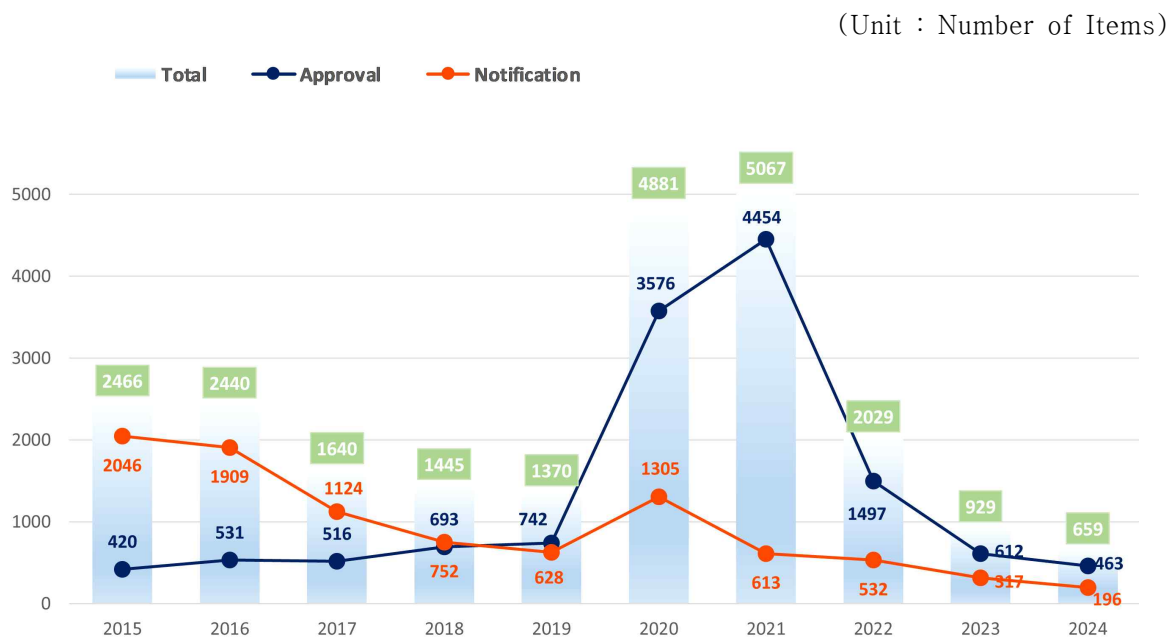


Fig.1

Manufacturing and Import Approval and Notification Status by Year(number of items, '15~'24)

When 2024 status was identified in terms of manufacturing and import, the proportion of approval notification was higher than notification with 403 items(71.6%) in manufacturing for approval and 60 items(65.2%) in import for approval. The proportion of approval in all items increased compared to the previous year(about 65.9%, '23).

Table 3 Approval and Notification Status by Manufacturing and Import in 2024

(Unit : Number of Items)

Classification	Total	Manufacturing	Import
Approval	463	403 (71.6%)	60 (65.2%)
Notification	196	164 (28.9%)	32 (34.8%)
Total	659	567 (100%)	92 (100%)

When '24 status was classified by processing institution(head office, regional office), 427 items(92.2%) were handled by regional offices out of 463 items for approval, showing high percentage of processing by regional office, while the head office processing rate was 7.8%(36 cases) in '24, decreased by 11.2%(80 cases) compared to the previous year.

Table 4 Approval and Notification Status by Processing Institution in 2024

(Unit : Number of Items)

Classification	Total	Head Office	Regional Office
Approval	463	36 (7.8%)	427 (92.2%)
Notification	196	—	196
Total	659	36 (5.4%)	623 (94.5%)

When analyzing the handling status of regional offices in '24, 378 items were in manufacturing and 49 items in imports, out of 427 approval items of regional office, showing that manufacturing took most(88.5%) with 427 items(68.5%) for approval, slightly higher than 196 items(31.5%) for notification.

Table 5 Manufacturing and Import Status by Processing Institution in 2024

[Head Office]

(Unit : Number of Items)

Classification	Total	Manufacturing	Import
Approval	36	25	11
Total	36	25	11

[Regional Office]

(Unit : Number of Items)

Classification	Total	Manufacturing	Import
Approval	427 (68.5%)	378 (69.7%)	49 (60.5%)
Notification	196 (31.5%)	164 (30.3%)	32 (39.5%)
Total	623	542	81

When classifying the regional office status by 6 regional office, Daejeon Office processed the most with 240 items(38.5%), followed by Gyeongin office with 189 items(30.3%). 429 items processed in Gyeongin Office and Daejeon office were found to account for 68.8% of total processing status.

Table 6 Approval and Notification Status by Regional Office in 2024

(Unit : Number of Items)

Classification		Approval	Notification	Total
Regional Office	Daejeon office	203 (47.5%)	37 (18.9%)	240 (38.5%)
	Gyeongin office	104 (24.4%)	85 (43.4%)	189 (30.3%)
	Seoul office	68 (15.9%)	53 (27.0%)	121 (19.4%)
	Daegu office	23 (5.4%)	3 (1.5%)	26 (4.2%)
	Busan office	19 (4.4%)	7 (3.6%)	26 (4.2%)
	Gwangju office	10 (2.3%)	11 (5.6%)	21 (3.4%)
Total		427 (68.5%)	196 (31.5%)	623 (100.0%)

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

When examining the present status of top 5 quasi-drug items approved or notified in 2024, menstrual pad(41.1%), toothpaste(19.3%) and adhesive bandage(10.5%) held dominant positions, followed by filtering respirator and external disinfectant. When comparing the approval and notification rate by items, most of the top items recorded high approval ratios, while toothpaste recorded notification rate 2 times higher than approval rate.

Table 7 Top 5 Quasi-Drug Items Approval and Notification Status in 2024

(Unit : Number of Items)

Code Total	Menstrual pad [3110]	Toothpaste [4140]	Adhesive bandage [3380]	Filtering respirator [3220]	External disinfectant [4600]	Others
659	271 (41.1%)	127 (19.3%)	69 (10.5%)	43 (6.5%)	25 (3.8%)	124 (18.8%)
Approval	263	42	48	38	15	57
Notification	8	85	21	5	10	67

When examining approval and notification status by classification number in 2024, top 5 items took 81.2% of total. Besides, anti-droplet mask(2.7%) and mouth freshener(2.7%) were found to be approved and notified in the order named.

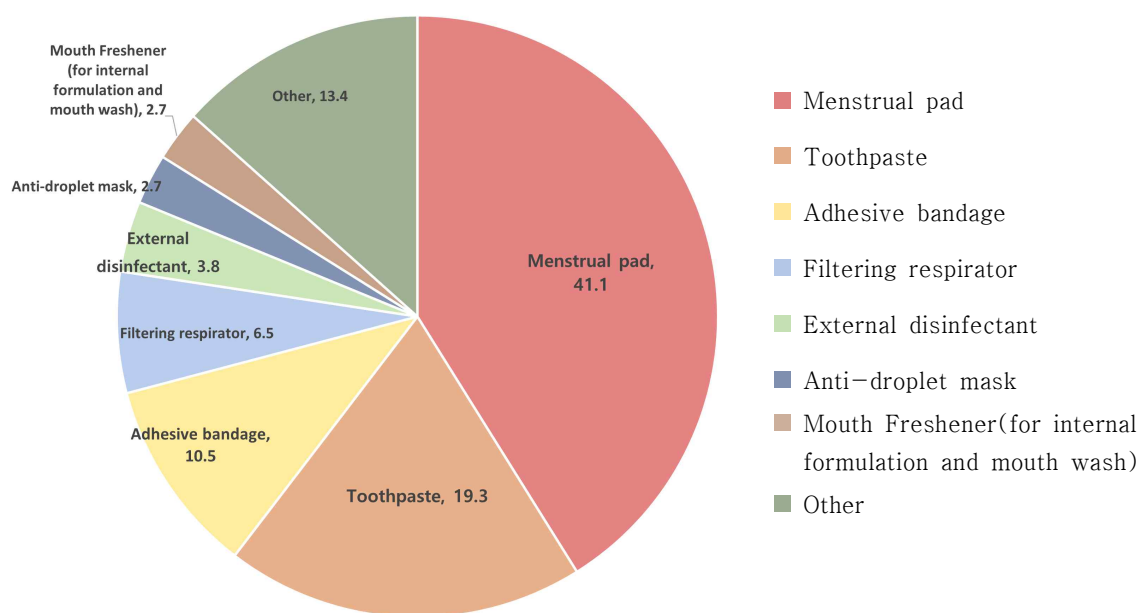


Fig. 2 Approval and Notification Distribution by Classification Number in 2024

When comparing the approval and notification status by classification number in 2024 with that of 2023, filtering respirator decreased about 5 times compared to the previous year, while toothpaste maintained a similar level to the previous year so that ranking changed from 2023.

3 types of quasi-drug masks including filtering respirator (filtering respirator, anti-droplet mask, surgical mask) approval and notification were 64 items, accounting for 9.7% of total in 2024.

Compared to 2023, the overall number of mask items decreased significantly (-79.0%). In particular, filtering respirators were 43 items in 2024, showing the highest reduction rate, down 80.4% from 2022 (220 items).

Table 8 Approval and Notification Status by Classification Number('23~'24)

(Unit : Number of Items)

Year	Menstrual pad [3110]	Toothpaste [4140]	Adhesive bandage [3380]	Filtering Respirator [3220]	External Disinfectant [4600]	Anti-droplet Mask [3230]	Mouth Freshener [4110]	Surgical Mask [3210]	Others	Total
'24	271 (41.1%)	127 (16.1%)	69 (6.7%)	43 (23.7%)	25 (3.0%)	18 (7.0%)	18 (2.0%)	3 (2.3%)	88 (13.4%)	659
'23	313 (33.7%)	150 (16.1%)	62 (6.7%)	220 (23.7%)	28 (3.0%)	65 (7.0%)	19 (2.0%)	21 (2.3%)	51 (5.5%)	929

Table 9 shows the detailed status of 659 quasi-drug items approved and notified in 2024 by classification number.

Table 9 Detailed Status of Approval and Notification by Classification Number in 2024

Classification	Classification Number		Number of Items
Article A*	3110	Menstrual Pad	271
	3120	Menstrual Tampon	7
	3130	Menstrual Cup	3
	3210	Surgical Mask	3
	3220	Filtering Respirator	43
	3230	Anti-droplet Mask	18
	3330	Elastic Bandage	6
	3360	Absorbent Gauze	9
	3370	Absorbent Cotton	6
	3380	Adhesive Bandage	69
Subtotal			435
Article B**	4110	Mouth Freshener (For internal use and mouthwash)	18
	4140	Toothpaste	127
	4320	Repellent	7
	4400	Contact Lens Care Product	16
	4600	External disinfectant	25
	4713	External Spray Pas	2
	4721	Low-content Vitamin and Mineral Agent	5

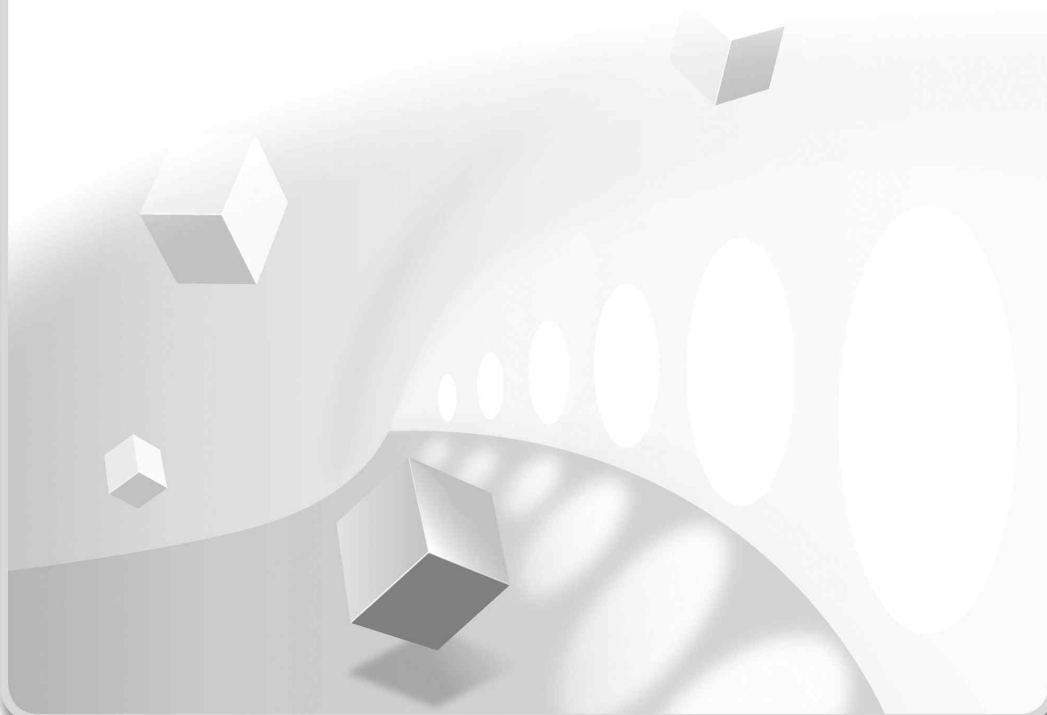
Classification	Classification Number		Number of Items
	4722	Nutrients, Tonic and Alternative Agent(for internal liquid only)	1
	4830	Anti-snooring Agent(aid)	1
	4840	Teeth Whitener	6
	4850	Product used for cleaning or disinfecting denture(false teeth), dental braces, etc.	3
	Subtotal		211
Items similar to Article A and B	3510	Non-adhesive product used for absorbing exudate from the affected area	6
	3520	Sterilized goods used during surgical procedure for prevention of infection	1
	3530	Items similar to Article A	1
	3600	Items used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)	4
	4920	Portable product containing air composition or oxygen manufactured to be breathed in by person	1
	Subtotal		13
Total			659

* Items falling under Article A of Subparagraph 7 of Article 2 of the Pharmaceutical Affairs Act

** Items falling under Article B of Subparagraph 7 of Article 2 of the Pharmaceutical Affairs



Detailed Status of Quasi-Drug Approval in 2024



2. Detailed Status of Quasi-Drug Approval in 2024 ●●●

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

Among 463 items for approval in '24, quasi-drugs under Article A were 371 items(80.1%), quasi-drugs under Article B were 79 items(17.1%), and quasi-drugs similar to Article A and Article B were 13 items(2.8%). That is, quasi-drug under Article A take most of items and the number of such drugs decreased compared to the previous year, and the number of quasi-drug under Article B increased, and those of quasi-drugs similar to Article A and Article B increased about 1.5 times compared to the previous year.

Table 10 Approval Status by Article of Quasi-Drugs('23~'24)

(Unit : Number of Items)

Year	Total	Article A	Article B	Article C*	Items similar to Article A and B
'24	463	371 (80.1%)	79 (17.1%)	—	13 (2.8%)
'23	612	551 (90.0%)	53 (8.7%)	—	8 (1.3%)

* Pesticide for disinfection in Article C and B of Subparagraph 7, Article 2 of Pharmaceutical Affairs Act were transferred to the Ministry of Environment on Jan. 1, 2019

Among the quasi-drugs approved in '24, the quasi-drugs subject to safety and efficacy review were 36 items(25 items for manufacturing(69.4%), 11 items for import (30.6%)), which was 3.2 times decrease compared to '23. It showed similar level as the previous year, considering the recent trends of approval for safety and efficiency examination (53 items(in '20) → 20 items(in '21) → 32 items(in '22) → 116 items('23) → 36 items('24)).

Table 11 Status of Approval Subject to Safety and Efficacy Review by Manufacturing and Import('23~'24)

(Unit : Number of Items)

Year	Total	Manufacturing	Import
'24	36	25(69.4%)	11(30.6%)
'23	116	109(94.0%)	7(6.0%)

When analyzing 36 items subject to safety and efficiency examination approved in 2024 by article, there were 18 items of Article A quasi-drugs (11 menstrual pads, 1 menstrual cup, 3 filtering respirators and 3 adhesive bandages), 15 items of Article B quasi-drugs (1 mouth freshener, 8 toothpastes, 3 repellents, 2 contact lens care products, 1 item of detergent or disinfectant of denture(false teeth), and 3 items of quasi-drugs similar to Article A and B(Products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth))). Among them, menstrual pad, the Article A quasi-drug accounted for the high proportion at 30.5%(11 items), and Article B quasi-drugs accounted for 22.2%(8 items).

Table 12 Status of Approval Subject to Safety and Efficacy Review by Article in 2024

No.	Type	Items	Number of Items Approved
1	Article A Quasi-Drug	Menstrual Pad	11
		Menstrual Cup	1
		Filtering Respirator	3
		Adhesive Bandage	3
2	Article B Quasi-Drug	Mouth Freshener (For internal use and mouthwash)	1
		Toothpaste	8
		Repellent	3
		Contact Lens Care Products	2
		Preparation for cleaning and disinfection denture(false teeth), dental braces and other removable oral devices	1
3	Quasi-Drug similar to Article A and Article B	Products used for hygiene management of bleeding immediately after childbirth and lochia(vaginal discharge after childbirth)	3
Total			36

2.1. Article A Quasi-Drug Approval Status

Article A quasi-drugs are the products that fall on 'Fibers, rubber products or similar products used for the purpose of treating, alleviating or preventing human or animal disease', including menstrual pad, mask and gauze.

In terms of Article A quasi-drug approval status in '24, menstrual pad recorded the most with 263 items(70.9%), followed by 48 items(12.9%) of adhesive bandage and 38 items (10.2%) of filtering respirator and 12 items(3.2%) of anti-droplet mask.

Table 13 Article A Quasi-Drug Approval Status in 2024

Items		Approval (number)
Menstrual Hygiene Management Product	Menstrual pad	263
	Menstrual Cup	3
Mask	Filtering respirator	38
	Anti-droplet mask	12
Product used for preservation protection and treatment of the affected area	Elastic Bandage	5
	Gauze	2
	adhesive bandage	48
Total		371

1) Menstrual Hygiene Management Product

Menstrual hygiene management products include menstrual pads, menstrual tampons and menstrual cups. In 2024, 266 items(263 items of menstrual pad, 3 items of menstrual cup) were approved.

Among the menstrual hygiene management products approved in 2024, 11 items of menstrual pad were subject to safety and efficiency examination, which corresponds to equivalent to new efficiency*. These items were examined since they mixed new materials with diversified formulations to the ingredients with existing example of uses for improvement of consumer comfort of wearing and absorption.

* Equivalent to new efficiency : Scope of submission of examination data of Article A quasi-drug subject to safety and efficiency examination since the product composition (name of raw material and purpose of mixing) is not the same as those of products already approved or notified.

Table 14 Status of Approval Subject to Menstrual Hygiene Management Product Safety and Efficacy Review in 2024

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	헤이즈슬림핏오버나이트팬티형중형	미래생활(주)	2024-01-22	[3110] Menstrual pad	Equivalent to new efficacy
2	Mfg.	헤이즈슬림핏오버나이트팬티형대형	미래생활(주)	2024-01-22	[3110] Menstrual pad	Equivalent to new efficacy
3	Mfg.	헤이즈네이처오버나이트팬티형중형	미래생활(주)	2024-01-23	[3110] Menstrual pad	Equivalent to new efficacy
4	Mfg.	헤이즈네이처오버나이트팬티형대형	미래생활(주)	2024-01-23	[3110] Menstrual pad	Equivalent to new efficacy

No.	Mfg./ Import	Product	Company	Approval date	Classificati on no.	Remarks
5	Mfg.	화이트수퍼흡수프레스이중형	유한킴벌리(주)	2024-09-27	[3110] Menstrual pad	Equivalent to new efficacy
6	Mfg.	화이트수퍼흡수프레스대형	유한킴벌리(주)	2024-09-27	[3110] Menstrual pad	Equivalent to new efficacy
7	Mfg.	쏘피내추럴순면커버중형	엘지유니참(주)	2024-10-17	[3110] Menstrual pad	Equivalent to new efficacy
8	Mfg.	1.시크릿데이순한코튼커버 슬림핏에디션중형, 2.시크 릿데이순한코튼커버슬림핏 에디션대형	주식회사하이베러	2024-12-05	[3110] Menstrual pad	Equivalent to new efficacy
9	Mfg.	1.시크릿데이순한코튼커버 슬림핏입는오버나이트에디 션중대형, 2.시크릿데이순 한코튼커버슬림핏입는오버 나이트에디션특대형	주식회사하이베러	2024-12-05	[3110] Menstrual pad	Equivalent to new efficacy
10	Mfg.	쏘피내추럴순면커버대형	엘지유니참(주)	2024-12-19	[3110] Menstrual pad	Equivalent to new efficacy
11	Impo rt	쏘피내추럴순면커버슈퍼롱	엘지유니참(주)	2024-12-19	[3110] Menstrual pad	Equivalent to new efficacy

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

2) 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 2024, 50 items(38 items of filtering respirator, 12 items of anti-droplet mask) were approved.

Among the items approved in 2024, 3 items were subject to safety and efficacy review, corresponding to equivalent to new efficacy(2 items) and new usages(1 item).

These items were approved after safety and efficacy review as the filtering respirator with a close-fitting function or the mask contains materials derived materials derived from plants and have been used in existing masks.

Table 15 Status of Approval Subject to Mask Safety and Efficacy Review in 2024

No.	Mfg./ Import	Product	Company	Approval date	Classificat ion no.	Remarks
1	Mfg.	마 이 크 로 에 어 핏 마 스 크 (KF99)(밀착형)(특대형, 흰 색)	(유)건영크린텍	2024-05-28	[3220] Filtering respirator	New usage
2	Mfg.	크리넥스라이트핏에코보건 용마스크(KF94)(대형, 흰색)	유한킴벌리(주)	2024-09-30	[3220] Filtering respirator	Equivalent to new efficacy
3	Mfg.	크리넥스라이트핏에코보건 용마스크(KF80)(대형, 흰색)	유한킴벌리(주)	2024-10-02	[3220] Filtering respirator	Equivalent to new efficacy

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

3) Products Used for Preservation, Protection and Treatment of Affected Areas

Products used for preservation, protection and treatment of affected areas include eye patch, bandage, elastic bandage, gauze, adhesive bandage, etc. In 2024, 55 items(48 items of adhesive bandage, 5 items of elastic bandage, and 2 items of gauze) were approved.

Among the approved products, 3 items of adhesive bandages were subject to safety and efficacy review, which correspond to new material (1 item) and equivalent to new efficacy (2 items), respectively.

These items are new materials without prior use of raw materials, or the materials with prior use but different composition of product including the purpose of mixing raw material, and approved after safety and efficacy review.

Table 16

Status of Approval Subject to Safety and Efficacy Review of Products Used for Preservation, Protection and Treatment of Affected Areas in 2024

No.	Mfg./Import	Product	Company	Approval date	Classification no.	Remarks
1	Import	듀라포어서지컬테이프	한국쓰리엠(주)	2024-03-29	[3380] Adhesive bandage	New materials
2	Mfg.	위터락에스습윤방수밴드(멸균)	(주)한웅메디칼	2024-05-28	[3380] Adhesive bandage	Equivalent to new efficacy
3	Import	1. 마이크로포어서지컬테이프(탄), 2. 마이크로포어서지컬테이프(화이트)	한국쓰리엠(주)	2024-11-18	[3380] Adhesive bandage	Equivalent to new efficacy

* Approval information of each product(efficacy, effect, duration for usage, 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-drugs are the products that correspond to ‘non-appliance, non-machinery or similar articles that have insignificant influence on or do not directly act on human bodies’, including mouth freshener, toothpaste or contact lens care product, etc.

In terms of Article B quasi-drug approval status in 2024, toothpaste recorded the most with 42 items(53.2%), followed by 15 items(19.0%) of external disinfectant, and 7 items (8.9%) of mouth freshener.

Table 17 Article B Quasi-drug Approval Status in 2024

Item		Approval (number)
Prevention of bad breath, etc. products	Mouth Freshener(For internal use and mouthwash)	7
	Pastes	42
Repellent for mosquitoes, ticks, etc. applied to the human body for health of human	Repellent	3
Smoking cessation aids(except the products containing nicotine and tobacco(leaf tobacco))	Contact lens care product	3
External disinfectant		15
Formulation used for oral hygiene, etc.	Teeth Whitener	6
	Products used for cleaning and disinfecting denture(false teeth), dental braces and other removable oral devices	3
Total		79

1) Prevention of bad breath, etc. Products

Prevention of bad breath, etc. products include mouth freshener, toothpaste, etc. and 49 items (7 items of mouth freshener, 42 items of pastes) were approved in 2024.

Among the approval of Prevention of bad breath, etc. products in 2024, 9 items(1 item of mouth freshener, 8 items of toothpaste), a combination preparation with new composition(4 items) or combination preparation with increased or decreased contents (4 items) or single agent(1 item) were subject to safety and efficacy review.

These items were approved after safety and efficacy review as an item with new combination of raw materials used as active ingredients already in toothpastes, etc., or an item with increased or decreased contents of active ingredients or an item with single agent of active ingredients.

Table 18 Status of Approval Subject to Safety and Efficacy Review of Prevention of Bad Breath, etc. Products in 2024

No	Mfg./Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	1.페리오엑스치약, 2.페리오키즈펄핑1450치약딸기향, 3.페리오키즈펄핑1450치약포도향, 4.엄마치약이투명해요1450치약, 5.페리오키즈펄핑1450치약민트향	(주)엘지생활건강	2024-01-09	[4140] Toothpaste	Complex preparation with variation contents
2	Import	1.잭앤질어린이내추럴치약(이산화규소), 2.잭앤질어린이내추럴치약스트로베리향(이산화규소), 3.잭앤질어린이내추럴치약바나나향(이산화규소),	코스메디칼솔루션리서치	2024-01-29	[4140] Toothpaste	Single agent

No	Mfg./ Import	Product	Company	Approval date	Classificat ion no.	Remarks
		4.잭앤질어린이내추럴치약블랙커런트향(이산화규소), 5.잭앤질어린이내추럴치약블루베리향(이산화규소), 6.잭앤질어린이내추럴치약라즈베리향(이산화규소)				
3	Mfg.	페리오엠디치약	(주)엘지생활건강	2024-02-15	[4140] Toothpaste	Complex preparation with variation contents
4	Mfg.	시린탁효플러스치약	(주)엘지생활건강	2024-02-27	[4140] Toothpaste	Complex preparation with variation contents
5	Mfg.	1.치주시린탁효플러스치약, 2.메디케어잇몸치약후레쉬민트, 3.메디케어잇몸치약클린민트, 4.명약원프리미엄잇몸시린이케어치약	(주)엘지생활건강	2024-07-05	[4140] Toothpaste	Complex preparation with new composition
6	Import	1.퍼스트엠버콜게이트그레이트레귤러플레이버투스페이스트, 2.퍼스트엠버콜게이트후레쉬쿨민트투스페이스트	퍼스트엠버 주식회사	2024-08-07	[4140] Toothpaste	Complex preparation with variation contents
7	Mfg.	에이치에프티치약	(주)아모레퍼시픽	2024-11-20	[4140] Toothpaste	Complex preparation with new composition
8	Mfg.	1.페리오미백가글, 2.유시몰 화이트닝퍼플렉터가글, 3.유시몰화이트닝가글	(주)엘지생활건강	2024-11-20	[4110] Mouth freshener	Complex preparation with new composition
9	Mfg.	페리오엘엠치약	(주)엘지생활건강	2024-12-19	[4140] Toothpaste	Complex preparation with new composition

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

2) Other Article B Quasi-Drugs

As Article B quasi-drugs except the prevention of bad breath, etc. products, 30 items (3 items of repellent, 15 items of external disinfectant, 6 items of teeth whitener, 2 items of denture(false teeth) detergent · disinfectant) were approved in 2024. 6 items (3 items of repellent, 2 items of contact lens care product, 1 item of denture(false teeth) detergent · disinfectant) were subject to safety and efficacy review.

Among the quasi-drugs subject to safety and efficacy review, denture(false teeth) detergent and disinfectant was approved after safety and efficacy review with increased contents of raw materials already used as active ingredient; contact lens care products were approved due to changes in contents of active ingredients or change in usage or dosage compared to previously approved products.

The repellent is a product corresponding to the Article C, No. 2 of 'Designation of Scope of Quasi-drug according to Article 21, Paragraph 2 (7) of Regulation on Quasi-Drug Approval, Notification and Examination and were approved after safety and efficacy review.

Table 19

Status of Approval Subject to Safety and Efficacy Review of Other Article B Quasi-Drug in 2024

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
1	Import	모스키토밀크에스액(디에틸톨루아미드)	신신제약(주)	2024-01-12	[4320] Repellent	Other preparations
2	Mfg.	모스케어썩액(에틸부틸아세틸아미노프로피오네이트)	주식회사서우	2024-02-21	[4320] Repellent	Other preparations
3	Mfg.	폴리덴트맥스파워클린의치세정제	헤일리온코리아 주식회사	2024-03-05	[4850] A preparation intended for cleaning and disinfecting the goods attached/detached in the oral cavity including dentures (false teeth) and braces	Complex with increased or decreased contents
4	Mfg.	다비치렌즈플러스액(염화나트륨)	주식회사 휴메디솔	2024-07-05	[4400] Contact lens care product	Other preparations
5	Mfg.	해피홈모기기피제패밀리액(에틸부틸아세틸아미노프로피오네이트)	(주)유한양행	2024-08-05	[4320] Repellent	Other preparations
6	Mfg.	아이원케어단백질제거액(프로테아제)	주식회사 휴메디솔	2024-09-02	[4400] Contact lens care product	Other preparations

* Approval information of each product(efficacy, effect, duration for usage, 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-drugs 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 ▲ Goods used to temporarily adjust the color of teeth by applying to the surface of teeth ▲ Portable goods used for human inhalation with temporary supply of air or oxygen before or after mountain climbing or exercise ▲ Products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)((generally called 'mother pad') ▲ Goods similar to Article A, Subparagraph 7, Article 2 of 「Pharmaceutical Affairs Act」 .

13 items were approved including non-adhesive goods(6 items), products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)(4 items), sterilized items used for surgical procedures for the purpose of prevention of infection, etc., portable product (1 item) as quasi-drug similar to Article A and Article B in 2024.

Table 20 Status of Approval of Quasi-Drug Similar to Article A and Article B in 2024

Item	Approval(number)
Non-adhesive goods used for absorbing the exudate, etc. from the affected area	6
Sterilized items used for surgical procedures for the purpose of prevention of infection, etc.	1
Products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)	4
Portable product containing air composition or oxygen manufactured to be breathed in by person	1
Products similar to Article A	1
Total	13

Among approval of quasi-drugs similar to Article A and Article B, 3 items were new usage(2 items) or new efficacy(1 item), subject to safety and efficacy review. These items were made with new composition of products for improvement of user convenience and absorption by mixing materials used in menstrual pad into the maternal pad with similar purpose of use.

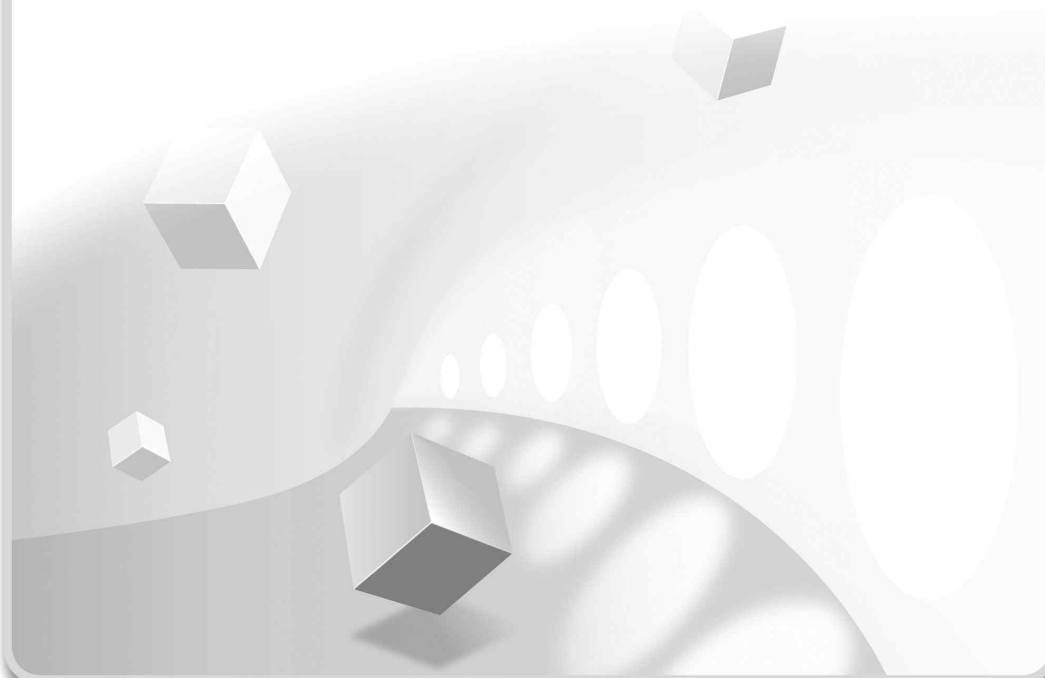
Table 21 Status of Approval Subject to Safety and Efficacy Review of Quasi-Drugs Similar to Article A and Article B in 2024

No.	Mfg./Import	Product	Company	Approval date	Classification no.	Remarks
1	Import	마더케이미라클산모패드	(주)마더케이	2024-01-03	[3600] Products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)	New usage
2	Mfg.	다솜맘케어산모패드	(주)서림	2024-01-04	[3600] Products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)	New usage
3	Mfg.	시크릿데이마더스이지팬티형	주식회사하이베리	2024-03-14	[3600] Products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)	New efficacy

* Approval information of each product(efficacy, effect, duration for usage, 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

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3.1. Quasi-Drug Approval Change Status

Looking at the status of top 5 items in terms of new approval since 2021, menstrual pad, mask(filtering respirator, anti-droplet mask), adhesive bandage, toothpaste has maintained top positions with slight fluctuation in the ranking. While mask(filtering respirator, surgical mask, anti-droplet mask) took the top position due to Covid 19 in 2021, menstrual has taken that position since 2021 when the market supply was stabilized. In 2024, anti-droplet mask fell from the top rankings and there was a fluctuation in the rankings of filtering respirator.

Table 22 Status of Top 5 Items Approved by Year('21~'24)

No.	2021		2022		2023		2024	
	Item	Number of items	Item	Number of items	Item	Number of items	Item	Number of items
1	Filtering respirator (3220)	2,819 (63.3%)	Filtering respirator (3220)	1,025 (68.5%)	Menstrual pad (3110)	233 (38.1%)	Menstrual pad (3110)	263 (56.8%)
2	Anti-droplet mask (3230)	1,076 (24.2%)	Anti-droplet mask (3230)	222 (14.8%)	Filtering respirator (3220)	204 (33.3%)	Adhesive bandage (3380)	48 (10.4%)
3	Menstrual pad (3110)	149 (3.3%)	Menstrual pad (3110)	115 (7.7%)	Anti-droplet mask (3230)	52 (8.5%)	Toothpaste (4140)	42 (9.1%)
4	Surgical mask (3210)	232 (5.2%)	adhesive bandage (3380)	52 (3.5%)	adhesive bandage (3380)	39 (6.4%)	Filtering respirator (3220)	38 (8.2%)
5	Adhesive bandage (3380)	78 (1.8%)	Toothpaste (4140)	24 (1.6%)	Toothpaste (4140)	28 (4.6%)	External disinfectant (4600)	15 (3.2%)
Item approval (number)		4,454 (100%)		1,497 (100%)		612 (100%)		463 (100%)

Looking at the quasi-drug approval change status by year, new item approval for masks(surgical mask, filtering respirator, anti-droplet mask) used as a personal infection protective products was 4,127 in 2021, an increase from 2020 due to COVID 19, accounting for 92.6% of total approval of 4,454 items.

In 2022, as the supply and demand of disinfection was stabilized and mandatory wearing of masks was gradually eased, the number of new approval of related products sharply decreased compared to the previous year. In particular, anti-droplet masks decreased by 854 items compared to 2021, recording the highest rate of decrease (79.3%).

In 2023, as the decrease trend of approval and notification of disinfection products continued from the previous year, the number of new approval was about 46% (929 items) compared to the previous year, while the approval items subject to safety and efficiency review have increased 3.6 times compared to the previous year, with diversification trend of development of quasi-drugs closely related to daily life such as menstrual pad and toothpastes.

In 2024, as the downward trend in approval and notification continued from the previous year, the number of new items decreased by about 24.3% (463 items) compared to the previous year.

Analyzing the trend of quasi-drug approval in terms of approval rate by quasi-drug classification number, filtering respirator had shown absolute superiority as new approval was concentrated on it as the

personal infection product in 2021-22. However, approval for various items was found to be more balanced in 2023 compared to the previous year, due to activation of development of quasi-drugs frequently used in daily life with increased interest in personal health and downward adjustment of the infectious disease crisis level since the end of 2022. In 2024, approvals had been given for various product groups as it had continued from the previous year.

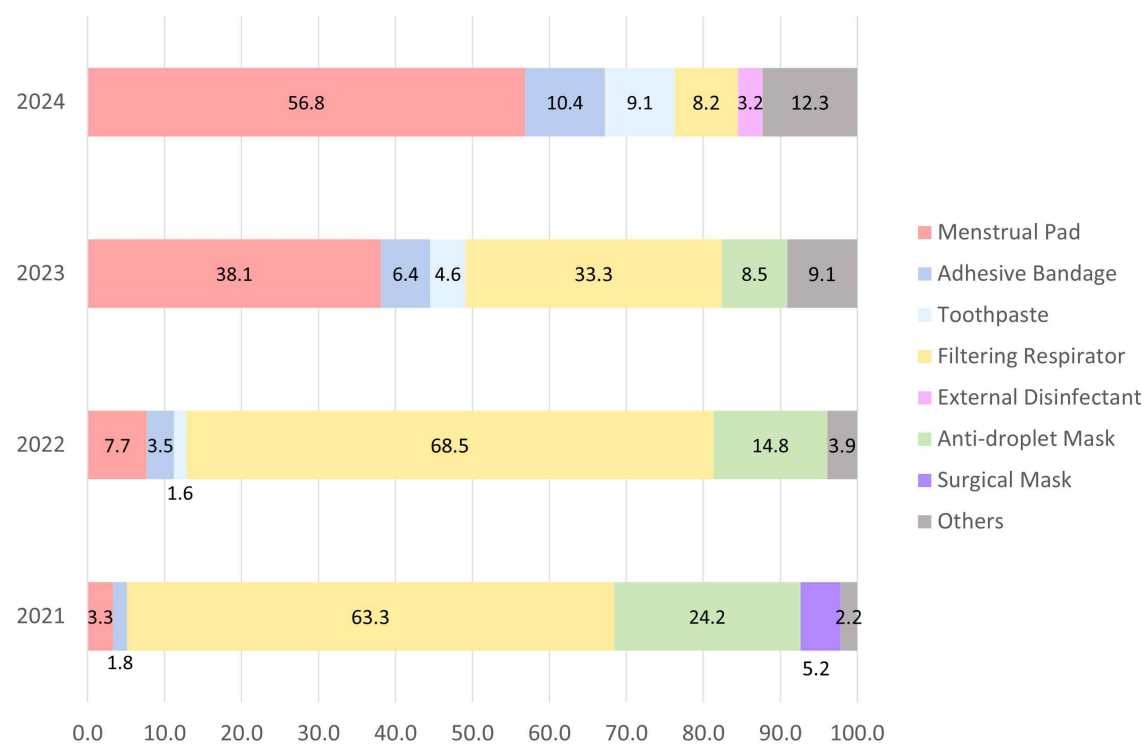


Fig.3 Percentage of Approval by Year and Quasi-Drug Classification Number ('21~'24)

3.2. Changes in Management of Quasi-Drug Approval Review

The Ministry of Food and Drug Safety has continuously expanded designation of the scope of quasi-drugs and prepared management system to preemptively secure safety of the consumers. The following are the major improvements to the annual approval and notification system for the domestic quasi-drug.

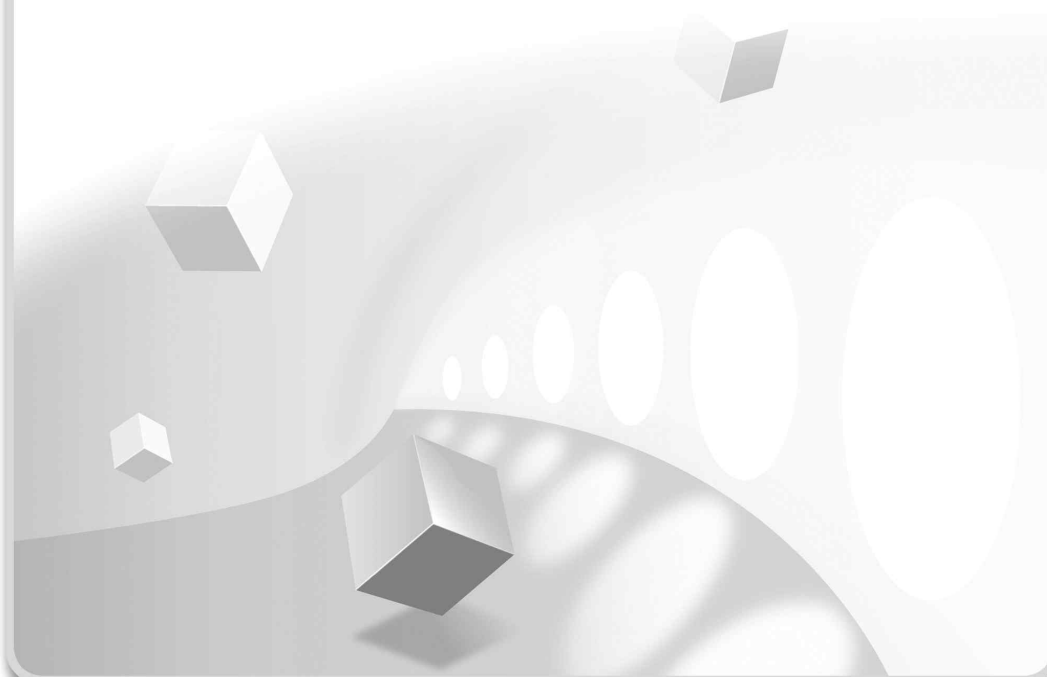
2020	<ul style="list-style-type: none"> • Respond to COVID 19 crisis - Newly establish ‘Anti-droplet Mask’ as a quasi drug * Revise ‘Designation of scope of quasi-drugs’ (June 1, 2020)
2021	<ul style="list-style-type: none"> • Improve quality of personal disinfection products - Prepare standard specifications for mask raw materials (Plastic Nose Wire, Ear Loops) * Establish specification on raw materials in ‘Korean Quasi-drug Codex (KQC)’ (Feb. 26, 2021) • Prepare for the carbon neutral era - Commence the quasi-drug electronic certificate of permission service without time or space restriction that can reduce paper use, is easy to manage (Oct. 29, 2021)
2022	<ul style="list-style-type: none"> • Support activation of market entry of quasi-drug mask - Establish standardization of quasi-drug mask of which approval has rapidly increased since the spread of COVID 19. * Create new specification on products (Filtering Respirator(KF94, KF80), Anti-droplet Mask, Surgical Mask) and materials (Nonwoven Fabric for Mask, Cotton Nonwoven Fabric) in ‘Korean Quasi-drug Codex (KQC)’ (Mar. 22, 2023.)

2023	<ul style="list-style-type: none"> • Reinforce connection between designation of scope of quasi-drug and classification number - Unify classification system of quasi-drugs similar to Article A and Article B * Newly establish classification number of Quasi-drugs similar to Article A or Article B according to Clause 4 of designation of scope of quasi-drugs in 'Regulation on Classification Number of Quasi-Drugs' (June 28, 2023)
2024	<ul style="list-style-type: none"> • Reflect current technology level in standards and testing methods of quasi-drugs. - Improve testing methods for menstrual blood hygiene products including menstrual pads and panty liners * Revision of 'Standards and Testing Methods for Quasi-Drugs'(Nov. 26, 2024) • Improve the efficiency of quasi-drug approval and notification management and expand safe use - Add toothpaste formulation (tablet) ※ 'New formulation(tablet) to 'Quasi-drug Manufacturing Standard (Oct. 21, 2024)

The Ministry of Food and Drug Safety will continue to establish new standards on quasi-drugs and to improve approval management system.

4

Appendix



Appendix I Overview of Quasi-Drug Approval/ 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 efficacy review or availability of process procedures for the products. An item that falls under any of the following categories should be subject to marketing notification:

(Article 8, (4) of 「Rules on Safety of Medicines, etc.」 (Prime Minister's Decree))

O 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

- O Items of which the standards and test methods are announced by the Minister of Food and Drug Safety
- O 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 23 Status of Departments Related to Quasi-Drug(as of Jun. 2025)

Classification	Department	Quasi-Drug Petition Name
Biopharmaceuticals and Herbal Medicine Bureau	Biopharmaceutical Policy Division (Bio Approval TF)	Quasi-Drug Manufacturing, Sales, Import Item(Change) Approval <ul style="list-style-type: none">• Items Subject to Safety·Efficacy Review
	Quasi-drugs Policy Division	<ul style="list-style-type: none">• Designation and classification of quasi-drugs• Quasi-drug GMP evaluation
National institute of Food and Drug Safety Evaluation	Biopharmaceuticals and Herbal Medicine Evaluation Dept.	Quasi-drug <ul style="list-style-type: none">• Safety and efficacy review• Standards and test method examination• Preview
	Cosmetics Evaluation Division	
Seoul Regional Office of Food and Drug Safety	Pharmaceutical Safety Management Division	Quasi-drug manufacturing (import) approval and notification (including change) <ul style="list-style-type: none">• Limited to items not subject to safety and efficacy review
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		

Appendix III

Quasi-Drug Manufacturing (Import) Approval/ Notification Procedure

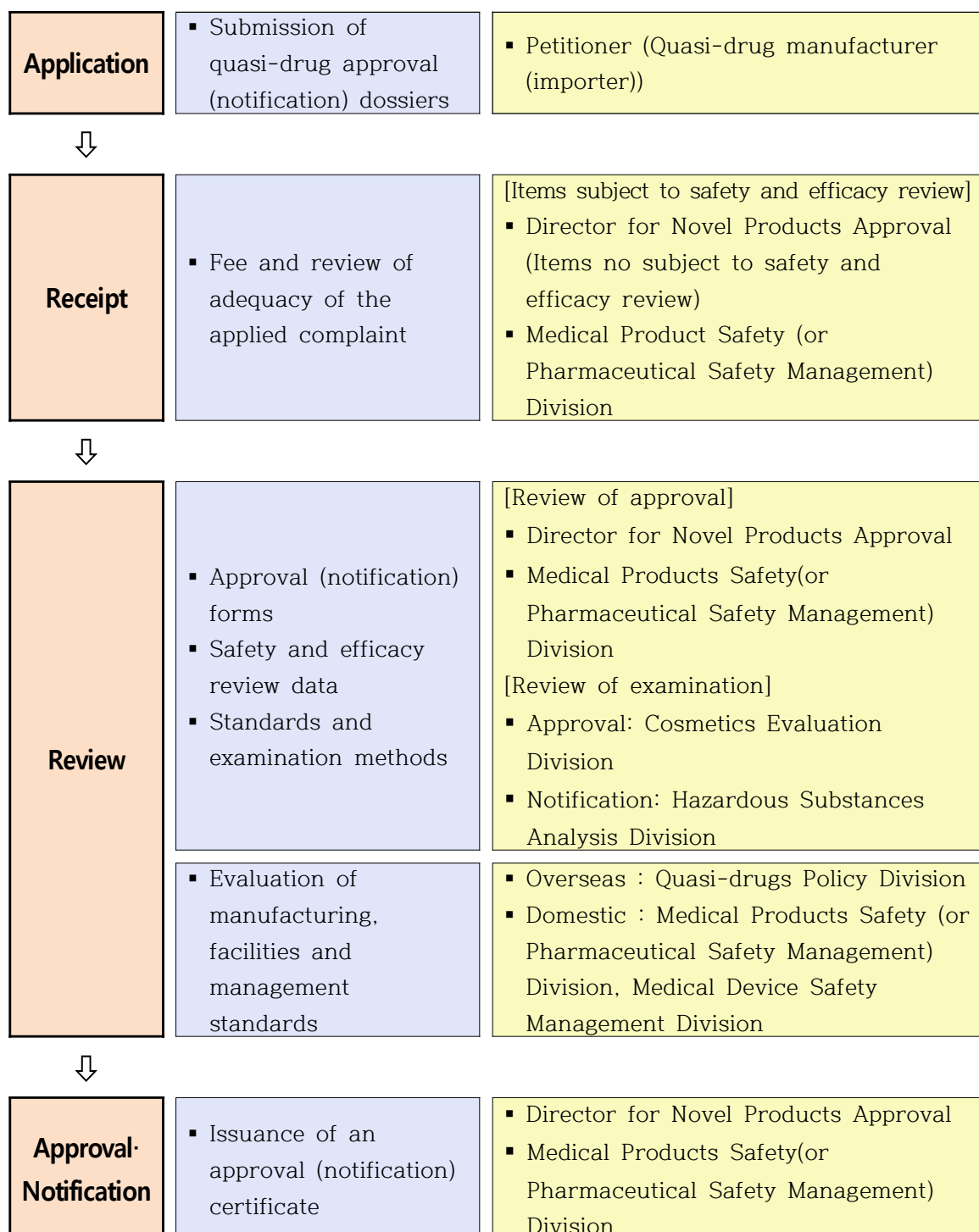


Fig. 4 Quasi-Drug Manufacturing(Import) Approval and Notification Procedure

Appendix IV

Quasi-Drug Approval/ Notification Status

Table 24 Quasi-Drug Manufacturing and Import Approval and Notification Status by year('21~'24)

(Unit : Number of Items)

Year	Total	Approval	Notification	Head office	Regional office	Mfg.	Import
'24	659	463 (70.3%)	196 (29.7%)	36 (5.5%)	623 (94.5%)	567 (86.0%)	92 (14.0%)
'23	929	612 (65.9%)	317 (34.1%)	116 (12.5%)	813 (87.5%)	861 (92.7%)	68 (7.3%)
'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%)

* Including cancellation or withdrawal, excluding for export

Table 25 Approval and Notification Status by Classification Number('21~'24)

(Unit : Number of Items)

Year	Menstrual pad [3110]	Toothpaste [4140]	adhesive bandage [3380]	Filtering respirator [3220]	External Disinfectant [4600]	Anti-drople Mask [3230]	Mouth freshener [4110]	Contact lens care product [4400]	Others	Total
'24	271 (41.1%)	127 (19.3%)	69 (10.5%)	43 (6.5%)	25 (3.8%)	18 (2.7%)	18 (2.7%)	16 (2.4%)	72 (10.9%)	659
'23	313 (33.7%)	150 (16.1%)	62 (6.6%)	220 (23.7%)	28 (3.0%)	66 (7.1%)	19 (2.0%)	3 (0.3%)	69 (7.4%)	929
'22	336 (16.6%)	122 (6.0%)	110 (5.4%)	1,087 (53.5%)	55 (2.7%)	232 (11.4%)	15 (0.7%)	5 (0.2%)	66 (3.2%)	2,029
'21	392 (7.7%)	128 (53.5%)	188 (3.7%)	2,819 (55.6%)	147 (2.9%)	1,076 (21.2%)	19 (0.3%)	5 (0.1%)	293 (5.7%)	5,067

※ Related Regulations

- ‘Designation of scope of quasi-drug’(MFDS Notice No. 2020-48, May 29, 2020)
- ‘Regulations on Quasi-Drug Classification Numbers’(MFDS Rule No. 191, June 28, 2023)

Table 26 Designation of the Scope and Classification Number of Quasi-Drug

Item(Classification Number)			Remarks
Group 1	A. Menstrual hygiene management products	1) Menstrual Pad(3110)	Fibers, rubber, etc used for hygiene purpose
		2) Menstrual Tampon(3120)	
		3) Menstrual Cup(3130)	
	B. Mask	1) Surgical Mask(3210)	
		2) Filtering Respirator(3220)	
		3) Anti-droplet Mask(3230)	
	C. Products used for preservation, protection and treatment, etc. of the affected area	1) Eye Bandage(3310)	
		2) Bandage(3320)	
		3) Elastic Bandage(3330)	
		4) Plaster Bandage(3340)	
		5) Tubular Compression Bandage (Stockinet)(3350)	
6) Absorbent Gauze(3360)			
7) Absorbent Cotton(3370)			
8) Adhesive Bandage(3380)			
Group 2	A. Prevention of bad breath, etc. products	1) Mouth Freshener(For internal use and mouthwash)(4110)	Products with weak action or without direct action on the human body
		2) Antiperspirant(For external use only)(4120)	
		3) Hot rash ·Skin erosion treatment product(4130)	
		4) Toothpaste(4140)	
	C. Repellent for mosquitoes, ticks, etc. applied to the human body for health of human (4320)		
	D. Contact Lens Care Product (4400)		

Item(Classification Number)		Remarks
	E. Products that do not contain nicotine, falling under the following criteria (excluding products containing tobacco(leaf tobacco))	1) Smoking Desire Reducer(4510) 2) Smoking Habit Improvement Aids(4520)
	F. External disinfectant directly used on the human body (4600) (Active ingredients: hydrogen peroxide, isopropyl alcohol, benzalkonium chloride, cresol or ethanol)	
	G. Ointment, cataplasma agent, External spray pas (prescribed by the quasi-drug manufacturing standards)	Ointment(4711)
		Cataplasma Agent(4712)
		External Spray Pas(4713)
	H. Products for internal use (prescribed by the quasi-drug manufacturing standards)	1) Low-content Vitamin and Mineral Agent(4721)
		2) Nutrients, Tonic and Alternatives Agent(For internal liquid only)(4722)
		3) Stomach Digestive Medicine(For internal liquid only)(4723) Intestinal drugs(For internal tablet only)(4724)
	I. Formulation used for oral hygiene, etc.	1) Tooth Root Canal Disinfectant(For external liquid only)(4810)
		2) Products used to prevent hand sucking in infants and children (External liquid, powder, etc.)(4820)
		3) Anti-snoring Agent(aid)(4830)
		4) Teeth Whitener (containing less than 3% hydrogen peroxide)(4840)
		5) Products used for cleaning and disinfecting denture(false teeth), dental braces(4850)
		6) Plaque(tongue plaque) dyeing(coloring) agent(4860)

Item(Classification Number)		Remarks
Group 4	A. Non-adhesive products such as pads, sponges, etc. used for absorbing the exudate, etc. from the affected areas (3510, newly established in June '23.)	Products similar to Group 1 and Group 2
	B. Sterilized products such as sterilized cotton swabs, sterilized gloves, etc. used during surgical procedure for prevention of infection (3520, newly established '23.6.)	
	C. Wet tissue for oral cleaning to clean teeth and gums (3400)	
	D. Products used to temporarily adjust the color of teeth by applying to the surface of teeth (4870)	
	E. Portable goods used for human insulation with temporary supply of air or oxygen before and after mountain climbing or exercise (4920)	
	F. Products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth) (3600, newly established in June '23.)	
	G. Products similar to group 1 (3530, Newly established '23.6.)	

2024 Quasi-Drug Approval Report

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Public Interest Whistleblower System

The Public Interest whistleblower Protection Act will protect your conscience.
If you find any wrongful act or experience unjustified treatments by officials of MFDS or concerned persons, please report to the webpage below. We promise to do our best to help ensure that the confidentiality of whistleblowers' identity is guaranteed and they will be protected from disadvantage of the future complaint treatment.

Public Interest Whistleblower Protection System?

The system aimed to protect those (including relatives and cohabitants) reporting any act that is detrimental to the public interest through confidentiality of their identity, protection from unjustified treatment and personal protection measures.

※For Protection Measures

MFDS' official website(www.mfds.go.kr)> Public Communication > e-People > Report Public Corruption