

Issuance Registration No.
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11-1471000-000394-10
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**2023**

# **Quasi-Drug Approval Report**

**Jun. 2024.**



**Ministry of Food and  
Drug Safety**

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

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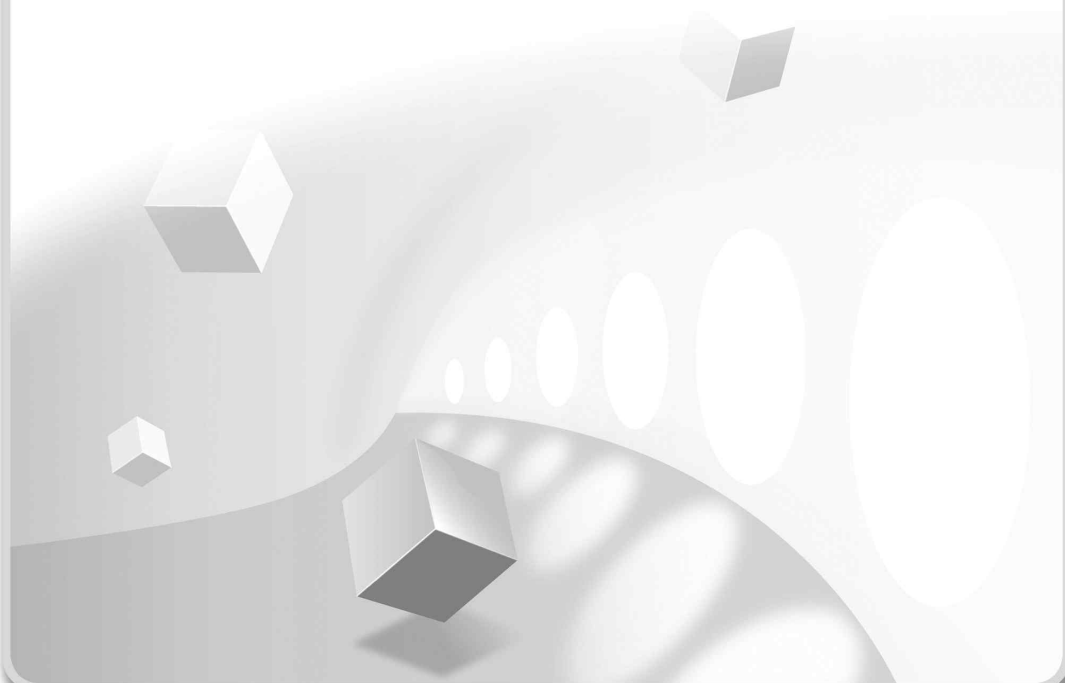
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# 1

## General Status of Quasi-Drug Approval (Notification) in 2023



## 1. General Status of Quasi-Drug Approval (Notification) in 2023

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 929 items in quasi-drug manufacturing or import approval and notification in 2023, which is 1,100 item (54.2%) decrease from 2,029 items in 2022.

Among them, there are 861 items (92.7%) in manufacturing and 68 items (7.3%) in import, which means that domestic manufacturing items are 13 times more than import items. There are 612 items (65.9%) in approval and 317 items (34.1%) in notification, which means that the number of approval items about 2 times of notification items.

By institution, 116 items (12.5%) were handled by head office, 813 items (87.5%) by regional office. The head office processing rate was less than 2% of the total in '22, but increased significantly in '23 as the number of items processed increased 4 times and total processing rate increased substantially to 8 times compared to the previous year, meaning that application for approval for items subject to safety and efficacy has

increased according to the diversification trend in development of quasi-drugs closely related to everyday life.

## 1.1. General Status

There are a total of 929 items in quasi-drug manufacturing and import approval and notification in '23. Compared to those in '22, there were 885 items (-59.1%) in total approval, meaning 1,184 item (-59.3%) decrease in approval and notification to regional office, and 1,076 item (-55.5%) decrease in manufacturing, and notification items have shown a continuous decreasing trend since 2015. .

When comparing the status of '23 in terms of domestic manufacturing and import, most of them corresponded to domestic manufacturing (92.7%), similar to '22, and the proportion of import slightly increased compared to the previous year.

**Table 1** Quasi-Drug Manufacturing (Import) Approval/ Notification Status ('22~'23)

(Unit : Number of Items)

Year	Total	Approval	Notification	Mfg.	Import	Head Office	Regional Office
'23	929	612 (65.9%)	317 (34.1%)	861 (92.7%)	68 (7.3%)	116 (12.5%)	813 (87.5%)
'22	2,029	1,497 (73.8%)	532 (26.2%)	1,937 (95.5%)	92 (4.5%)	32 (1.6%)	1,997 (98.4%)

\* Including cancellation or withdrawal, excluding for export



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 items (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.

**Table 2** Manufacturing (Import) Approval/ Notification Status by year

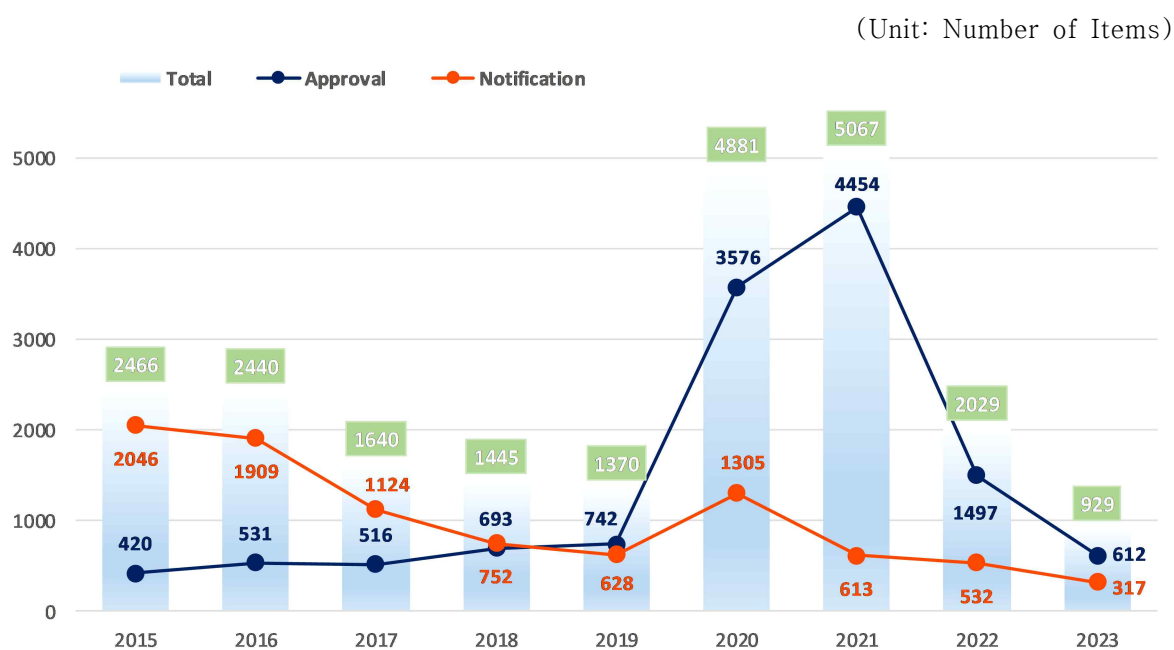
(Unit: Number of Items)

Classification	2015	2016	2017	2018	2019	2020	2021	2022	2023
Approval	420	531	516	693	742	3,576	4,454	1,497	<b>612 (65.9%)</b>
(Year-on-year increase %)	26.4	-2.8	34.3	7.1	381.9	24.6	-66.4		<b>-59.1</b>
Notification	2,046	1,909	1,124	752	628	1,305	613	532	<b>317 (34.1%)</b>
(Year-on-year increase %)	-6.7	-41.1	-33.1	-16.5	107.8	-53.0	-13.2		<b>-40.4</b>
Total	2,466	2,440	1,640	1,445	1,370	4,881	5,067	2,029	<b>929</b>
(Year-on-year increase %)	-1.1	-32.8	-11.9	-5.2	256.3	3.8	-60.0		<b>-54.2</b>

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 number of approval and notification items in 2023 was about 46% compared to the previous year, and the total number has decreased due to continued decrease trend in approval and notification of related disinfection products that continued from the previous year, but the proportion of items handled and approved by head offices after safety and efficacy review increased according to diversification of product development in quasi-drug industry.



**Fig. 1** Manufacturing (Import) Approval/ Notification Status by year  
(number of items, '15~'23)

When '23 status was identified in terms of manufacturing and import, the proportion of approval was higher than notification with 572 items (66.4%) in manufacturing for approval and 40 items (58.8%) in import for

approval, but the proportion of approval in all items rather decreased compared to the previous year (about 74%, '22).

**Table 3** Approval/ Notification Status by Manufacturing and Import in 2023

(Unit: Number of Items)

Classification	Total	Manufacturing	Import
Approval	612	572 (66.4%)	40 (58.8%)
Notification	317	289 (33.6%)	28 (41.2%)
Total	929	861 (100%)	68 (100%)

When '23 status was classified by processing institution (head office, regional office), 496 items (81.0%) were handled by regional offices out of 612 items for approval, showing high percentage of processing by regional office, while the head office processing rate was 2.1% (32 cases) the previous year but increased by 16.9% (84 cases) to 19.0% (116 cases) in 2023.

**Table 4** Approval/ Notification Status by Processing Institution in 2023

(Unit: Number of Items)

Classification	Total	Head Office	Regional Office
Approval	612	116 (19.0%)	496 (81.0%)
Notification	317	—	317
Total	929	116 (12.5%)	813 (87.5%)

Head office processing rate seems to have substantially increased as the approval subject to safety and efficiency examination increased according to the diversification of development of quasi-drug closely related to daily life and improvement of quality competitiveness of domestically manufactured products focusing on Covid 19 disinfection products.

When analyzing the handling status of regional offices in '23, 752 items were in manufacturing out of 813 approval items of regional office, and 61 items in imports, showing that manufacturing took most (92.5%), and 496 items (61.0%) for approval, slightly higher than that for notification.

**Table 5** Manufacturing and Import Status by Processing Institution in 2023

**[Head Office]**

(Unit: Number of Items)

Classification	Total	Manufacturing	Import
Approval	116	109	7
Total	116	109	7

**[Regional Office]**

(Unit: Number of Items)

Classification	Total	Manufacturing	Import
Approval	496 (61.0%)	463 (61.6%)	33 (54.0%)
Notification	317 (39.0%)	289 (38.4%)	28 (46.0%)
Total	813	752	61

When classifying the regional office status by 6 regional office, Gyeongin Office processed the most with 263 items (32.3%), followed by Daejeon office with 219 items (26.9%). 482 items processed in Gyeongin Office and Daejeon office were found to account for 59.2% of total processing status.

**Table 6** Approval and Notification Status by Regional Office in 2023

(Unit: Number of Items)

Classification		Approval	Notification	Total
Regional Office	Gyeongin office	170 (34.3%)	93 (29.3%)	263 (32.3%)
	Seoul office	82 (16.5%)	104 (32.8%)	186 (22.9%)
	Daejeon office	148 (29.8%)	71 (22.4%)	219 (26.9%)
	Daegu office	36 (7.3%)	25 (7.9%)	61 (7.5%)
	Busan office	29 (5.8%)	18 (5.7%)	47 (5.8%)
	Gwangju office	31 (6.3%)	6 (1.9%)	37 (4.6%)
Total		496 (61.0%)	317 (39.0%)	813 (100.0%)

## 1.2. Status of Approval and Notification by Classification Number

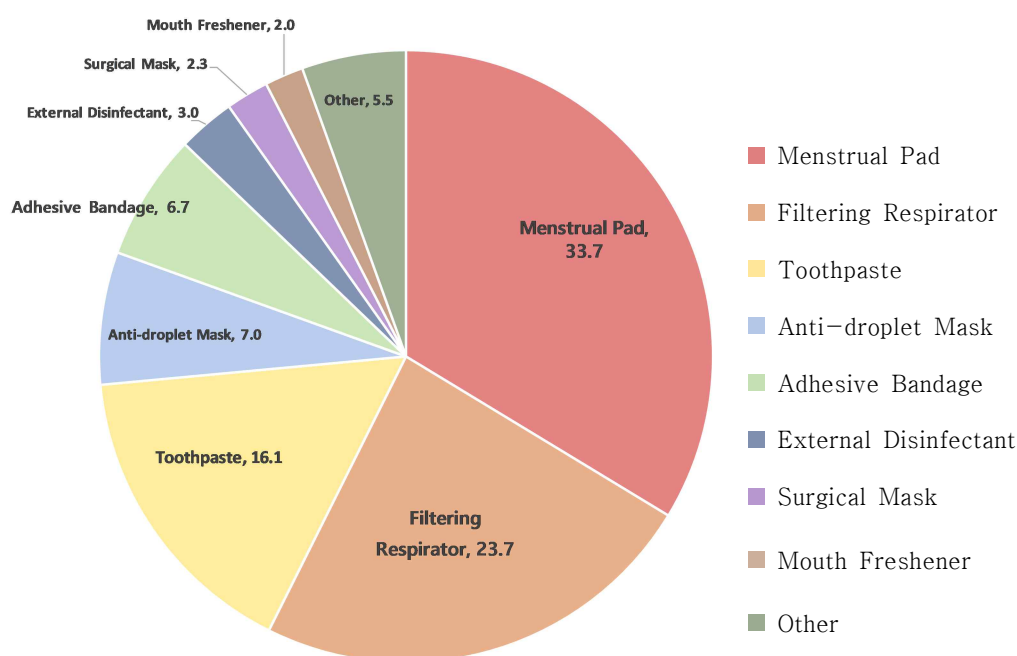
When examining the present status of top 5 quasi-drug items approved or notified in '23, menstrual pad (33.7%), filtering respirator (23.7%) and toothpaste (16.1%) held dominant positions, followed by anti-droplet mask and adhesive bandage. When comparing the approval and notification rate by items, most of the top items recorded high approval ratios, while toothpaste recorded notification rate 4.6 times higher than approval rate.

**Table 7** Top 5 Quasi-Drug Items Approval and Notification Status in 2023

(Unit: Number of Items)

Item Total	Menstrual Pad [3110]	Filtering Respirator [3220]	Toothpaste [4140]	Anti-droplet Mask [3230]	Adhesive Bandage [3380]	Others
929	313 (33.7%)	220 (23.7%)	150 (16.1%)	65 (7.0%)	62 (6.7%)	119 (12.8%)
Approval	233	204	28	52	39	56
Notification	80	16	122	13	23	63

When examining approval and notification status by classification number in '23, top 5 items took 87.1% of total. Besides, external disinfectant (3.0%), surgical mask (2.3%), mouth freshener (2.0%) were found to be approved and notified in the order named.



**Fig. 2** Approval and Notification Distribution by Classification Number in 2023

When comparing the approval and notification status by classification number in '23 with that of '22, menstrual pad and filtering respirator held dominant positions for 2 consecutive years, while filtering respirator decreased in '23 compared to the previous year, and menstrual pad kept the similar level as the previous year so that the ranking changed from '22.

3 types of quasi-drug masks (filtering respirator, anti-droplet mask, surgical mask) approval and notification were 306 items, accounting for 33.0% of total in 2023.

When comparing with '22, the overall number of mask items decreased significantly (-77.1%). In particular, filtering respirators were 220 items in '23, showing highest reduction rate, down 79.7% from '22 (1,086 items).

**Table 8** Approval and Notification Status by Classification Number ('22~'23)

(Unit: Number of Items)

Year	Menstrual Pad [3110]	Filtering Respirator [3220]	Toothpaste [4140]	Anti-droplet Mask [3230]	Adhesive Bandage [3380]	External Disinfectant [4600]	Surgical Mask [3210]	Mouth Freshener [4110]	Others	Total
'23	313 (33.7%)	220 (23.7%)	150 (16.1%)	65 (7.0%)	62 (6.7%)	28 (3.0%)	21 (2.3%)	19 (2.0%)	51 (5.5%)	929
'22	336 (16.6%)	1,086 (53.5%)	122 (6.0%)	233 (11.5%)	110 (5.4%)	55 (2.7%)	18 (0.9%)	16 (0.8%)	53 (2.6%)	2,029

Table 9 shows the detailed status of 929 quasi-drug items approved and notified in 2023 by classification number.

**Table 9** Detailed Status of Approval and Notification by Classification Number in 2023

Classification	Classification Number		Number of Items
Article A*	3110	Menstrual Pad	313
	3120	Menstrual Tampon	4
	3130	Menstrual Cup	2
	3210	Surgical Mask	21
	3220	Filtering Respirator	220
	3230	Anti-droplet Mask	65
	3320	Bandage	1
	3330	Elastic Bandage	3
	3360	Absorbent Gauze	4
	3370	Absorbent Cotton	2
	3380	Adhesive Bandage	62
Subtotal			697
Article B**	4110	Mouth Freshener (For internal use and mouthwash)	19



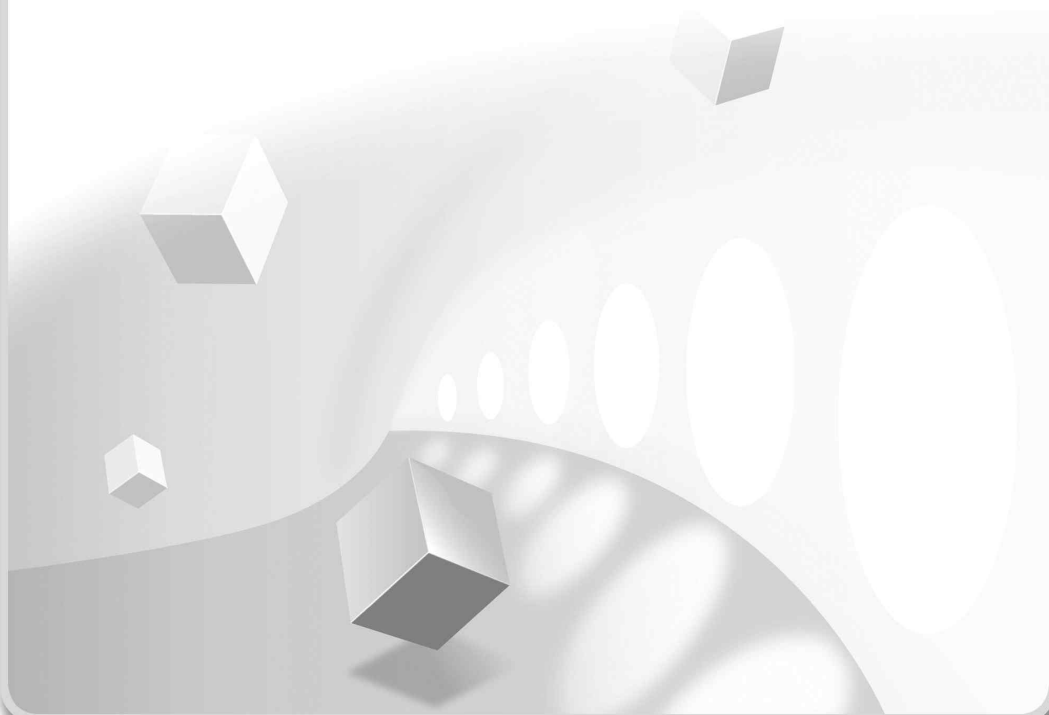
Classification	Classification Number		Number of Items
	4130	Heat rash· Skin erosion treatment product	1
	4140	Toothpaste	150
	4320	Repellent	3
	4400	Contact Lens Care Product	3
	4520	Smoking habit improvement aids	1
	4600	External Disinfectant	28
	4713	External Spray Pas	1
	4721	Low-content Vitamin and Mineral Agent	9
	4840	Teeth Whitener	4
	4850	Products used to cleaning or disinfecting denture(false teeth), dental braces, etc.	2
	Subtotal		221
	Items similar to Article A and B	3510	Non-adhesive products used for absorb exudate of the affected area
3530		Products Similar to Article A	2
3600		Products used for hygiene management of bleeding immediately after childbirth and lochia(vaginal discharge after childbirth)	2
4920		Portable products containing air composition or oxygen intended for human inhalation	1
Subtotal		11	
Total			929

\* 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

## 2

### Detailed Status of Quasi-Drug Approval in 2023



## 2. Detailed Status of Quasi-Drug Approval in 2023 ●●●

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 review depending on the type of review.

Among 612 items for approval in '23, quasi-drugs under Article A were 551 items (90.0%), quasi-drugs under Article B were 53 items (8.7%), and quasi-drugs similar to Article A and Article B were 8 items (1.3%). That is, quasi-drug under Article A take most of items and the number of such drugs significantly decreased compared to the previous year, but other than this, it was similar level as the previous year.

Table 10 Approval Status by Article of Quasi-Drugs ('22~'23)

(Unit: Number of Items)

Year	Total	Article A	Article B	Article C*	Items similar to Article A and B
'23	612	551 (90.0%)	53 (8.7%)	—	8 (1.3%)
'22	1,497	1,437 (96.0%)	51 (3.4%)	—	9 (0.6%)

\* Pesticides 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 '23, the quasi-drugs subject to safety and efficacy review were 116 items (109 items for manufacturing (94.0%), 7 items for import (6.0%)), which was 3.6 times increase compared to '22. It is a substantial increase, considering the recent trends of approval for safety and efficiency examination (53 items ('20) → 20 items ('21) → 32 items ('22) → 116 items('23)), meaning that development of new products in the industry is actively in progress.

**Table 11** Status of Approval Subject to Manufacturing (Import) Safety and efficacy review ('22~'23)

(Unit: Number of Items)

Year	Total	Manufacturing	Import
'23	116	109(94.0%)	7(6.0%)
'22	32	26(81.3%)	6(18.8%)

When analyzing 116 items subject to safety and efficacy review approved in '23, there are 101 quasi-drug items in Article A (92 items of menstrual pad, 5 items of filtering respirator, 4 items of anti-droplet mask), 15 quasi-drug items in Article B (2 items of mouth freshener, 7 items of toothpaste, 1 item of repellent, 1 item of smoking habit improvement aids, 1 item of denture (false teeth) cleaning · disinfectant, 3 items of quasi-drugs similar to Article A and B (1 items of non-adhesive product for absorbing exudate from the affected area, 2 items of hygiene management of bleeding and lochia immediately after childbirth). Among them, menstrual pad, the quasi-drug in Article A,

accounted for the highest proportion at 79.3% (92 items).

**Table 12** Status of Approval Subject to Safety and efficacy review by Article in 2023

No.	Classification	Item	Number of Items Approved
1	Article A	Menstrual Pad	92
		Filtering Respirator	5
		Anti–droplet Mask	4
2	Article B	Mouth Freshener (For internal use and mouthwash)	2
		Toothpaste	7
		Repellent	1
		Smoking Habit Improvement aids	1
		Products used to cleaning or disinfecting denture (false teeth), dental braces, etc.	1
3	Items similar to Article A and B	Non–adhesive products used to absorb exudate of the affected area	1
		Products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)	2
Total			116

## 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 treatment, alleviation, care or preventing human or animal disease', including menstrual pad, mask and absorbent gauze, etc.

In terms of Article A quasi-drug approval status in '23, menstrual pad recorded the most with 233 items (42.3%), followed by 204 items (37.0%) of filtering respirator and 52 items (9.4%) of anti-droplet mask and 39 items (7.1%) of adhesive bandage.

Table 13 Article A Quasi-Drug Approval Status in 2023

Item		Approval (number)
Menstrual hygiene management products	Menstrual Pad	233
	Menstrual Cup	2
Mask	Surgical Mask	18
	Filtering Respirator	204
	Anti-droplet Mask	52
Products used for preservation, protection and treatment, etc. of the affected area	Elastic Bandage	2
	Absorbent Gauze	1
	Adhesive Bandage	39
Total		551

## 1) Menstrual hygiene management products

Menstrual hygiene management products include menstrual pads, menstrual tampons and menstrual cups. In 2023, 235 items (233 items of menstrual pad, 2 items of menstrual cup) were approved.

Among the menstrual hygiene management products approved in 2023, 92 items of menstrual pad were subject to safety and efficiency examination, which correspond to new materials (5 items) or equivalent to new efficiency\* (87 items). 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 review data of Article A quasi-drug subject to safety and efficacy review since the product composition (name of raw material and purpose of mixing) is not the same as that of products already approved or notified.

**Table 14** Status of Approval Subject to Menstrual Hygiene Management Product Safety and efficacy review in 2023

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	좋은느낌좋은순면커버 라이너수퍼롱비	유한킴벌리(주)	2023-01-02	[3110] Menstrual Pad	New materials
2	Mfg.	에어컨브레스어게인중형 슬림	(주)레몬	2023-01-05	[3110] Menstrual Pad	New materials
3	Mfg.	좋은느낌유입는오버나이트 뉴중형	유한킴벌리(주)	2023-03-29	[3110] Menstrual Pad	Equivalent to new efficacy

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
4	Mfg.	좋은느낌 유입는오버나이트 뉴대형	유한킴벌리(주)	2023-03-29	[3110] Menstrual Pad	Equivalent to new efficacy
5	Mfg.	좋은느낌입는오버나이트 디대형	유한킴벌리(주)	2023-03-31	[3110] Menstrual Pad	Equivalent to new efficacy
6	Mfg.	좋은느낌입는오버나이트 디중형	유한킴벌리(주)	2023-03-31	[3110] Menstrual Pad	Equivalent to new efficacy
7	Mfg.	좋은느낌입는오버나이트 디소형	유한킴벌리(주)	2023-03-31	[3110] Menstrual Pad	Equivalent to new efficacy
8	Mfg.	좋은느낌오리지널입는 오버나이트대형	유한킴벌리(주)	2023-04-27	[3110] Menstrual Pad	Equivalent to new efficacy
9	Mfg.	좋은느낌오리지널입는 오버나이트중형	유한킴벌리(주)	2023-04-27	[3110] Menstrual Pad	Equivalent to new efficacy
10	Mfg.	좋은느낌오리지널입는 오버나이트소형	유한킴벌리(주)	2023-04-27	[3110] Menstrual Pad	Equivalent to new efficacy
11	Import	오가쉴입는오버나이트슬림	(주)한컴헬스케어	2023-05-04	[3110] Menstrual Pad	Equivalent to new efficacy
12	Import	오닉유순면커버입는 오버나이트프리	(주)쌍용씨앤비	2023-05-04	[3110] Menstrual Pad	Equivalent to new efficacy
13	Mfg.	좋은느낌입는오버나이트프 대형	유한킴벌리(주)	2023-05-08	[3110] Menstrual Pad	Equivalent to new efficacy
14	Mfg.	좋은느낌입는오버나이트 프중형	유한킴벌리(주)	2023-05-08	[3110] Menstrual Pad	Equivalent to new efficacy
15	Mfg.	좋은느낌입는오버나이트 프소형	유한킴벌리(주)	2023-05-08	[3110] Menstrual Pad	Equivalent to new efficacy
16	Mfg.	좋은느낌 유수퍼롱에어	유한킴벌리(주)	2023-05-10	[3110] Menstrual Pad	Equivalent to new efficacy



No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
17	Mfg.	좋은느낌 유수퍼롱나	유한킴벌리(주)	2023-05-10	[3110] Menstrual Pad	Equivalent to new efficacy
18	Mfg.	좋은느낌 유수퍼롱가	유한킴벌리(주)	2023-05-10	[3110] Menstrual Pad	Equivalent to new efficacy
19	Mfg.	좋은느낌 유슬림오버나이트 플러스가	유한킴벌리(주)	2023-05-11	[3110] Menstrual Pad	Equivalent to new efficacy
20	Mfg.	좋은느낌 좋은순면커버 수퍼롱가	유한킴벌리(주)	2023-05-11	[3110] Menstrual Pad	Equivalent to new efficacy
21	Mfg.	좋은느낌 유오버나이트에어	유한킴벌리(주)	2023-05-11	[3110] Menstrual Pad	Equivalent to new efficacy
22	Mfg.	좋은느낌 유오버나이트가	유한킴벌리(주)	2023-05-11	[3110] Menstrual Pad	Equivalent to new efficacy
23	Mfg.	좋은느낌 오버나이트가	유한킴벌리(주)	2023-05-11	[3110] Menstrual Pad	Equivalent to new efficacy
24	Mfg.	좋은느낌 수퍼롱가	유한킴벌리(주)	2023-05-11	[3110] Menstrual Pad	Equivalent to new efficacy
25	Mfg.	좋은느낌 좋은유수퍼롱가	유한킴벌리(주)	2023-05-12	[3110] Menstrual Pad	Equivalent to new efficacy
26	Mfg.	좋은느낌 내추럴수퍼롱가	유한킴벌리(주)	2023-05-12	[3110] Menstrual Pad	Equivalent to new efficacy
27	Mfg.	화이트네이처수퍼롱 오버나이트가	유한킴벌리(주)	2023-05-18	[3110] Menstrual Pad	Equivalent to new efficacy
28	Mfg.	화이트수퍼흡수수퍼롱 오버나이트가	유한킴벌리(주)	2023-05-18	[3110] Menstrual Pad	Equivalent to new efficacy
29	Mfg.	화이트수퍼흡수오버나이트가	유한킴벌리(주)	2023-05-18	[3110] Menstrual Pad	Equivalent to new efficacy

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
30	Mfg.	좋은느낌 유린넨수퍼롱가	유한킴벌리(주)	2023-05-18	[3110] Menstrual Pad	Equivalent to new efficacy
31	Mfg.	후아내추럴순면커버 오버나이트뉴	유한킴벌리(주)	2023-05-18	[3110] Menstrual Pad	Equivalent to new efficacy
32	Mfg.	화이트순한순면커버수퍼롱 오버나이트가	유한킴벌리(주)	2023-05-22	[3110] Menstrual Pad	Equivalent to new efficacy
33	Mfg.	화이트순한순면커버맥시 오버나이트가	유한킴벌리(주)	2023-05-22	[3110] Menstrual Pad	Equivalent to new efficacy
34	Mfg.	좋은느낌 유울트라날개 소형가	유한킴벌리(주)	2023-05-30	[3110] Menstrual Pad	Equivalent to new efficacy
35	Mfg.	좋은느낌 유울트라날개 중형가	유한킴벌리(주)	2023-05-30	[3110] Menstrual Pad	Equivalent to new efficacy
36	Mfg.	좋은느낌 좋은유대형날개가	유한킴벌리(주)	2023-05-30	[3110] Menstrual Pad	Equivalent to new efficacy
37	Mfg.	좋은느낌 유슬림날개대형 플러스가	유한킴벌리(주)	2023-06-01	[3110] Menstrual Pad	Equivalent to new efficacy
38	Mfg.	좋은느낌 유슬림날개대형 에어	유한킴벌리(주)	2023-06-01	[3110] Menstrual Pad	Equivalent to new efficacy
39	Mfg.	좋은느낌 유슬림날개중형 에어	유한킴벌리(주)	2023-06-01	[3110] Menstrual Pad	Equivalent to new efficacy
40	Mfg.	좋은느낌 유슬림대형날개나	유한킴벌리(주)	2023-06-01	[3110] Menstrual Pad	Equivalent to new efficacy
41	Mfg.	좋은느낌 유슬림중형날개나	유한킴벌리(주)	2023-06-01	[3110] Menstrual Pad	Equivalent to new efficacy
42	Mfg.	좋은느낌 유슬림날개대형가	유한킴벌리(주)	2023-06-01	[3110] Menstrual Pad	Equivalent to new efficacy

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
43	Mfg.	좋은느낌 유슬림날개중형가	유한킴벌리(주)	2023-06-01	[3110] Menstrual Pad	Equivalent to new efficacy
44	Mfg.	좋은느낌 유울트라날개 대형가	유한킴벌리(주)	2023-06-05	[3110] Menstrual Pad	Equivalent to new efficacy
45	Mfg.	좋은느낌 좋은유중형날개가	유한킴벌리(주)	2023-06-05	[3110] Menstrual Pad	Equivalent to new efficacy
46	Mfg.	화이트액티브라이너롱	유한킴벌리(주)	2023-06-05	[3110] Menstrual Pad	Equivalent to new efficacy
47	Mfg.	좋은느낌 좋은유라이너롱가	유한킴벌리(주)	2023-06-05	[3110] Menstrual Pad	Equivalent to new efficacy
48	Mfg.	좋은느낌 좋은순면커버 라이너일반비	유한킴벌리(주)	2023-06-07	[3110] Menstrual Pad	Equivalent to new efficacy
49	Mfg.	좋은느낌 좋은순면커버 라이너롱비	유한킴벌리(주)	2023-06-07	[3110] Menstrual Pad	Equivalent to new efficacy
50	Mfg.	좋은느낌오펠티라이너일반가	유한킴벌리(주)	2023-06-07	[3110] Menstrual Pad	Equivalent to new efficacy
51	Mfg.	좋은느낌오펠티라이너롱가	유한킴벌리(주)	2023-06-07	[3110] Menstrual Pad	Equivalent to new efficacy
52	Mfg.	좋은느낌오데일리라이너롱가	유한킴벌리(주)	2023-06-07	[3110] Menstrual Pad	Equivalent to new efficacy
53	Mfg.	좋은느낌오펠티라이너 수퍼롱가	유한킴벌리(주)	2023-06-07	[3110] Menstrual Pad	Equivalent to new efficacy
54	Mfg.	좋은느낌 좋은순면커버 라이너수퍼롱가	유한킴벌리(주)	2023-06-15	[3110] Menstrual Pad	Equivalent to new efficacy
55	Mfg.	코텍스좋은느낌순수중형 날개형가	유한킴벌리(주)	2023-06-15	[3110] Menstrual Pad	Equivalent to new efficacy

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
56	Mfg.	코텍스 좋은느낌순수대형 날개형가	유한킴벌리(주)	2023-06-15	[3110] Menstrual Pad	Equivalent to new efficacy
57	Mfg.	건강한순수한면입는 오버나이트(중형,대형)	(주)이앤더블유	2023-06-20	[3110] Menstrual Pad	Equivalent to new efficacy
58	Mfg.	아임오입는오버나이트 (중형, 대형)	(주)이앤더블유	2023-06-20	[3110] Menstrual Pad	Equivalent to new efficacy
59	Mfg.	화이트순한순면커버맥시 대형가	유한킴벌리(주)	2023-06-21	[3110] Menstrual Pad	Equivalent to new efficacy
60	Mfg.	화이트수퍼흡수맥시슬림 중형나	유한킴벌리(주)	2023-06-21	[3110] Menstrual Pad	Equivalent to new efficacy
61	Mfg.	화이트수퍼흡수맥시슬림 대형나	유한킴벌리(주)	2023-06-21	[3110] Menstrual Pad	Equivalent to new efficacy
62	Mfg.	화이트네이처맥시대형 날개형가	유한킴벌리(주)	2023-06-21	[3110] Menstrual Pad	Equivalent to new efficacy
63	Mfg.	좋은느낌에이슬림대형가	유한킴벌리(주)	2023-06-27	[3110] Menstrual Pad	Equivalent to new efficacy
64	Mfg.	좋은느낌 좋은순면커버 대형가	유한킴벌리(주)	2023-06-27	[3110] Menstrual Pad	Equivalent to new efficacy
65	Mfg.	티키입는오버나이트베이지 (중형,대형)	(주)이앤더블유	2023-06-28	[3110] Menstrual Pad	Equivalent to new efficacy
66	Mfg.	티키입는오버나이트화이트 (중형,대형)	(주)이앤더블유	2023-06-28	[3110] Menstrual Pad	Equivalent to new efficacy
67	Mfg.	티키무유코입는오버나이트 화이트(중형,대형)	(주)이앤더블유	2023-06-28	[3110] Menstrual Pad	Equivalent to new efficacy
68	Mfg.	내츄럴코튼입는 오버나이트오(중형,대형)	(주)이앤더블유	2023-06-28	[3110] Menstrual Pad	Equivalent to new efficacy

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
69	Mfg.	르프레시대형팬티형생리대	(주)이앤더블유	2023-07-03	[3110] Menstrual Pad	Equivalent to new efficacy
70	Mfg.	르프레시중형팬티형생리대	(주)이앤더블유	2023-07-03	[3110] Menstrual Pad	Equivalent to new efficacy
71	Mfg.	아임이입는오버나이트대형	(주)이앤더블유	2023-07-03	[3110] Menstrual Pad	Equivalent to new efficacy
72	Mfg.	디어스킨리얼모달입는오버 나이트(중형,대형)	(주)이앤더블유	2023-07-07	[3110] Menstrual Pad	Equivalent to new efficacy
73	Mfg.	좋은느낌내추럴울트라날개 대형가	유한킴벌리(주)	2023-07-13	[3110] Menstrual Pad	Equivalent to new efficacy
74	Mfg.	좋은느낌내추럴울트라날개 중형가	유한킴벌리(주)	2023-07-13	[3110] Menstrual Pad	Equivalent to new efficacy
75	Mfg.	좋은느낌좋은유라이너 수퍼롱가	유한킴벌리(주)	2023-07-25	[3110] Menstrual Pad	Equivalent to new efficacy
76	Mfg.	좋은느낌좋은유라이너 일반가	유한킴벌리(주)	2023-07-25	[3110] Menstrual Pad	Equivalent to new efficacy
77	Mfg.	뉴내츄럴코튼리올윙대형	(주)레몬	2023-07-26	[3110] Menstrual Pad	Equivalent to new efficacy
78	Mfg.	뉴내츄럴코튼리올윙중형	(주)레몬	2023-07-26	[3110] Menstrual Pad	Equivalent to new efficacy
79	Mfg.	잇츠미입는오버나이트대형	(주)에스에스케이	2023-08-09	[3110] Menstrual Pad	Equivalent to new efficacy
80	Mfg.	잇츠미입는오버나이트중형	(주)에스에스케이	2023-08-09	[3110] Menstrual Pad	Equivalent to new efficacy
81	Mfg.	에어퀸오리진플러스울트라 슬림중형	(주)레몬	2023-08-10	[3110] Menstrual Pad	Equivalent to new efficacy

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
82	Mfg.	에어퀸오리진플러스울트라 슬림대형	(주)레몬	2023-08-10	[3110] Menstrual Pad	Equivalent to new efficacy
83	Mfg.	단색컴포트에어오버나이트 생리팬티	(주)단색	2023-08-23	[3110] Menstrual Pad	New materials
84	Mfg.	단색컴포트에어하이웨스트 생리팬티	(주)단색	2023-08-23	[3110] Menstrual Pad	New materials
85	Mfg.	단색컴포트에어브리프 생리팬티	(주)단색	2023-08-23	[3110] Menstrual Pad	New materials
86	Mfg.	뉴내츄럴코튼시그니처입는 오버나이트(중형,대형)	(주)이앤더블유	2023-09-07	[3110] Menstrual Pad	Equivalent to new efficacy
87	Mfg.	마리솜산리오캐릭터즈리얼 소프트입는오버나이트대형	중원(주)	2023-09-27	[3110] Menstrual Pad	Equivalent to new efficacy
88	Mfg.	마리솜산리오캐릭터즈리얼 소프트입는오버나이트중형	중원(주)	2023-09-27	[3110] Menstrual Pad	Equivalent to new efficacy
89	Mfg.	리버티센시티브입는 오버나이트대형	(주)서림	2023-11-09	[3110] Menstrual Pad	Equivalent to new efficacy
90	Mfg.	리버티센시티브입는 오버나이트중형	(주)서림	2023-11-14	[3110] Menstrual Pad	Equivalent to new efficacy
91	Mfg.	리버티심리스입는 오버나이트코튼커버대형	(주)서림	2023-11-23	[3110] Menstrual Pad	Equivalent to new efficacy
92	Mfg.	리버티심리스입는 오버나이트코튼커버중형	(주)서림	2023-11-23	[3110] Menstrual Pad	Equivalent to new efficacy

\* Approved information of each product (efficacy/effectiveness, direction for use, 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 2023, 274 items (18 items of surgical mask, 204 items of filtering respirator, 52 items of anti-droplet mask) were approved.

Among the items approved in 2023, 9 items (5 items of filtering respirator, 4 items of anti-droplet mask) were subject to safety and efficacy review, corresponding to new materials (3 items), new usages (5 items) or equivalent to new efficacy (1 item).

These items were approved after safety and efficacy review as the mask in a material and form different from existing one, including the mask in the shape with transparent window that allows to check the shape of a person's mouth as well as a mask in the structure that can play a role of nose piece instead of nose piece materials (plastic covering wire, aluminum, etc.).

Table 15 Status of Approval Subject to Mask Safety and efficacy review in 2023

No.	Mfg./Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	델큐어투명창비말차단용 마스크(KF-AD)(대형)	(주)버드앰	2023-04-19	[3230] Anti-droplet Mask	Equivalent to new efficacy
2	Import	리앤웰미세먼지와이어리스 입체마스크(KF94)(중형) (흰색,검정색)	(주)나옴케어	2023-06-13	[3220] Filtering Respirator	New usage
3	Mfg.	아에르제로비말차단용마스크(KF-AD)(중형)	(주)씨앤티스	2023-06-29	[3230] Anti-droplet Mask	New materials

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
4	Mfg.	크리넥스와이드핏에코보건용 마스크(KF94)(대형)(흰색)	유한킴벌리(주)	2023-08-16	[3220] Filtering Respirator	New materials
5	Mfg.	크리넥스와이드핏에코보건용 마스크(KF80)(대형)(흰색)	유한킴벌리(주)	2023-08-16	[3220] Filtering Respirator	New materials
6	Mfg.	카오스비말차단마스크(KF-AD) (대형)	(주)피앤엘	2023-09-08	[3230] Anti-droplet Mask	New usage
7	Mfg.	카오스코편없는비말차단 마스크(KF-AD)(대형)	(주)피앤엘	2023-09-08	[3230] Anti-droplet Mask	New usage
8	Mfg.	카오스코편없는보건용항사 방역마스크(KF94)(대형)	(주)피앤엘	2023-09-08	[3220] Filtering Respirator	New usage
9	Mfg.	카오스보건용항사방역마스크 (KF94)(대형)	(주)피앤엘	2023-09-08	[3220] Filtering Respirator	New usage

\* Approved information of each product (efficacy/effectiveness, 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-drugs are the products that correspond to ‘non-appliance, non-machinery or similar articles that have insignificant influence on or do not directly act upon human bodies’, including mouth freshener (for internal use and mouthwash), toothpaste or smoking cessation aids, etc.

In terms of Article B quasi-drug approval status in 2023, toothpaste recorded the most with 28 items (52.8%), followed by 10 items (18.9%) of external disinfectant, and 7 items (13.2%) of mouth freshener.

**Table 16** Article B Quasi-drug Approval Status in 2023

Items		Approval (number)
Prevention of bad breath, etc. Products	Mouth Freshener (For Internal use and mouthwash)	7
	Heat rash·Skin erosion Treatment Products	1
	Toothpaste	28
Repellent for mosquitoes, ticks, etc. applied to the human body for health of human	Repellen	1
Smoking cessation aids (excluding products containing nicotine, tobacco (leaf tobacco))	Smoking Habit Improvement aids	1
External disinfectant directly used on the human body	External Disinfectant	10

Items		Approval (number)
Formulation used for oral hygiene, etc.	Teeth Whitener	3
	Products used to cleaning or disinfecting denture (false teeth), dental braces, etc.	2
총 계		53

## 1) Prevention of bad breath, etc. Products

Prevention of bad breath, etc. products include mouth freshener, heat rash·skin erosion treatment products and toothpaste, etc. In 2023, 36 items (7 items of mouth freshener, 1 item of heat rash·skin erosion treatment product, 28 items of toothpastes) were approved.

Among the approval of prevention of bad breath, etc. products in 2023, 9 items (2 items of mouth freshener, 7 items of toothpaste), preparation containing new substance (1 item), a complex preparation with new composition (4 items) or complex preparation with variation(increase or decrease) contents (4 items) were subject to safety and efficacy review.

These items were made by newly combining the materials used as active ingredients already in toothpastes etc. or by mixing the the substance that has been used as an active ingredient of drug or the substance that has been mixed as an additive, into toothpastes and mouth freshener as active ingredients, and were approved after safety and efficacy review.

Table 17 Status of Approval Subject to Prevention of bad breath, etc. Products Safety and efficacy review in 2023

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	페리오퀵데오가글	(주)엘지생활건강	2023-01-11	[4110] Mouth Freshener	Complex preparation with new composition

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
2	Import	센소다인엑스트라답클린치약	(주)글락소스미스 클라인컨슈머 헬스케어코리아	2023-02-24	[4140] Toothpaste	Complex preparation with variation contents
3	Mfg.	2080엘가글	애경산업(주)	2023-04-21	[4110] Mouth Freshener	Complex preparation with new composition
4	Mfg.	2080다이치약	애경산업(주)	2023-05-19	[4140] Toothpaste	preparation containing new substance
5	Mfg.	2080잇몸케어치약	애경산업(주)	2023-06-20	[4140] Toothpaste	Complex preparation with variation contents
6	Mfg.	엠씨이치약	(주)아모레퍼시픽	2023-08-04	[4140] Toothpaste	Complex preparation with new composition
7	Import	라카루트액티브치약	주식회사 미향메드	2023-08-17	[4140] Toothpaste	Complex preparation with new composition
8	Import	센소다인컴플리트프로텍션플 러스치약	(주)글락소스미스 클라인컨슈머 헬스케어코리아	2023-09-07	[4140] Toothpaste	Complex preparation with variation contents
9	Import	1.큐라프록스1450(워터멜론향), 2.큐라프록스1450(민트향)	코스메디칼 솔루션리서치	2023-10-13	[4140] Toothpaste	Complex preparation with variation contents

\* Approved information of each product (efficacy/effectiveness, direction for use, 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 preventive oral care products, 17 items (1 item of repellent and smoking habit improvement aids, 10 items of external disinfectant, 3 items of teeth whitening solution, 2 items of denture (false teeth) cleaning · disinfectant) were approved in 2023. 1 item each of repellent, smoking habit improvement aids and denture (false teeth) cleaning · disinfectant was subject to safety and efficacy review.

Among the quasi-drugs subject to safety and efficacy review, denture (false teeth) cleaning · disinfectant was approved after safety and efficacy review by updating the composition and formulation of active ingredients. Smoking habit improvement aids was designated as the quasi-drug for safety management of the products as the 'tobacco substitute' was deleted from '「Tobacco Business Act」', and was approved after safety and efficacy review in 2023 according to scope of submission of new preparation.

**Table 18** Status of Approval Subject to Other Article B Quasi-drugs Safety and efficacy review in 2023

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	페리오콕폼클리너	(주)엘지생활건강	2023-01-16	[4850] denture(false teeth) cleaning· disinfectant	Complex preparation with new composition

No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
2	Mfg.	세스코마이랩모기기피제 (에틸부틸아세틸아미노 프로피오네이트)	(주)씨비티	2023-08-21	[4320] repellent	Other preparation
3	Mfg.	마샤퍼프	(주)마샤	2023-11-21	[4520] smoking habit improvement aids	New preparation

\* Approved information of each product (efficacy/effectiveness, 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 B

Quasi-drugs similar to Article A or Article B are the product that fall on No. 4 of 'Designation of Scope of Quasi-Drug' (MFDS Notice), including ▲Non-adhesive products used to absorb exudate of the affected area ▲Sterilized products use for surgical treatment for the purpose of infection prevention ▲Wet tissue for oral hygiene ▲Products used to temporarily adjust the color of teeth by applying to the surface of teeth ▲Portable products containing air composition or oxygen intended for human inhalation ▲Products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)(generally called 'mother pad') ▲Products similar to Article A, subparagraph 7, Article 2 of 「Pharmaceutical Affairs Act」 .

8 items were approved including non-adhesive goods (4 items), mother pad (2 items), portable product (1 item) as quasi-drug similar to Article A and Article B in 2023.

Table 19 Status of Approval of Quasi-Drug Similar to Article A and Article B in 2023

Item	Approval(number)
Non-adhesive products used to absorb exudate of the affected area	4
Products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)	2
Portable products containing air composition or oxygen intended for human inhalation	1
Products similar to Article A	1
Total	8

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 20** Status of Approval Subject to Quasi-drug Similar to Article A and Article B Safety and efficacy review in 2023

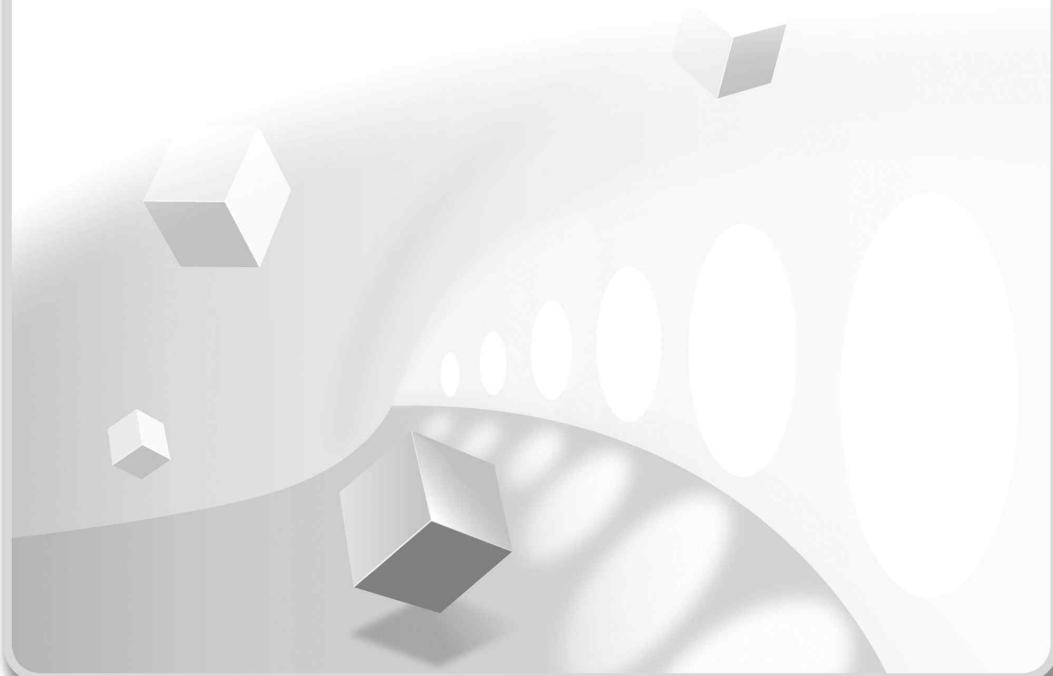
No.	Mfg./ Import	Product	Company	Approval date	Classification no.	Remarks
1	Mfg.	디펜드맘스안심패드형 에이	유한킴벌리(주)	2023-05-18	[3600] Products used for hygiene management of bleeding immediately after childbirth and lochia	New usage
2	Mfg.	디펜드맘스안심팬티형 에이	유한킴벌리(주)	2023-06-05	[3600] Products used for hygiene management of bleeding immediately after childbirth and lochia	New usage
3	Mfg.	메디솅넛플러스	(주)원바이오젠	2023-12-26	[3510] Non-adhesive products used to absorb exudate of the affected area	New efficacy

\* Approved information of each product (efficacy/effectiveness, 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

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#### 3.1. Quasi-Drug Approval Change Status

Table 21 Status of Top 5 Items Approved by Year ('20~'23)

No.	2020		2021		2022		2023	
	Item	Number of items	Item	Number of items	Item	Number of items	Item	Number of items
1	Filtering Respirator (3220)	1,651 (46.2%)	Filtering Respirator (3220)	2,819 (63.3%)	Filtering Respirator (3220)	1,025 (68.5%)	Menstrual Pad (3110)	233 (38.1%)
2	Anti-droplet Mask (3230)	1,214 (33.9%)	Anti-droplet Mask (3230)	1,076 (24.2%)	Anti-droplet Mask (3230)	222 (14.8%)	Filtering Respirator (3220)	204 (33.3%)
3	Surgical Mask (3210)	408 (11.4%)	Menstrual Pad (3110)	149 (3.3%)	Menstrual Pad (3110)	115 (7.7%)	Anti-droplet Mask (3230)	52 (8.5%)
4	Menstrual Pad (3110)	114 (3.2%)	Surgical Mask (3210)	232 (5.2%)	Adhesive Bandage (3380)	52 (3.5%)	Adhesive Bandage (3380)	39 (6.4%)
5	External disinfectant (4600)	52 (1.5%)	Adhesive Bandage (3380)	78 (1.8%)	Toothpaste (4140)	24 (1.6%)	Toothpaste (4140)	28 (4.6%)
Approval (number)		3,576 (100%)		4,454 (100%)		1,497 (100%)		612 (100%)

Looking at the status of top 5 items in terms of new approval since 2020, menstrual pad, mask (filtering respirator, surgical mask, anti-droplet mask), adhesive bandage, toothpaste has maintained top positions with slight changes in ranking. While external disinfectant took the top ranking due to Covid 19 in 2020, toothpaste has taken that

position since 2021 when the market supply was stabilized.

Looking at the quasi-drug approval change status by year, new item approval for external disinfectant and masks (surgical mask, filtering respirator, anti-droplet mask) used as a personal infection products substantially increased due to COVID 19 in 2020, reaching 3,325 items and taking 93% of total approval of 3,576 items.

In 2021, new approval of mask, an essential disinfection item, increased to 4,127 items, increase of 802 items compared to 2020 as the COVID 19 pandemic continued, accounting for 81.4% of the total 5,067 items.

In 2022, as the supply and demand of disinfection-related product 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 mask decreased by 843 items, compared to 2021, recording the highest rate of decrease (72.4%).

In 2023, as the decrease trend of approval and notification of disinfection-related 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 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.

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 2020-22, while approval for various items was found to be more balanced in 2023 compared to the previous year as the 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.

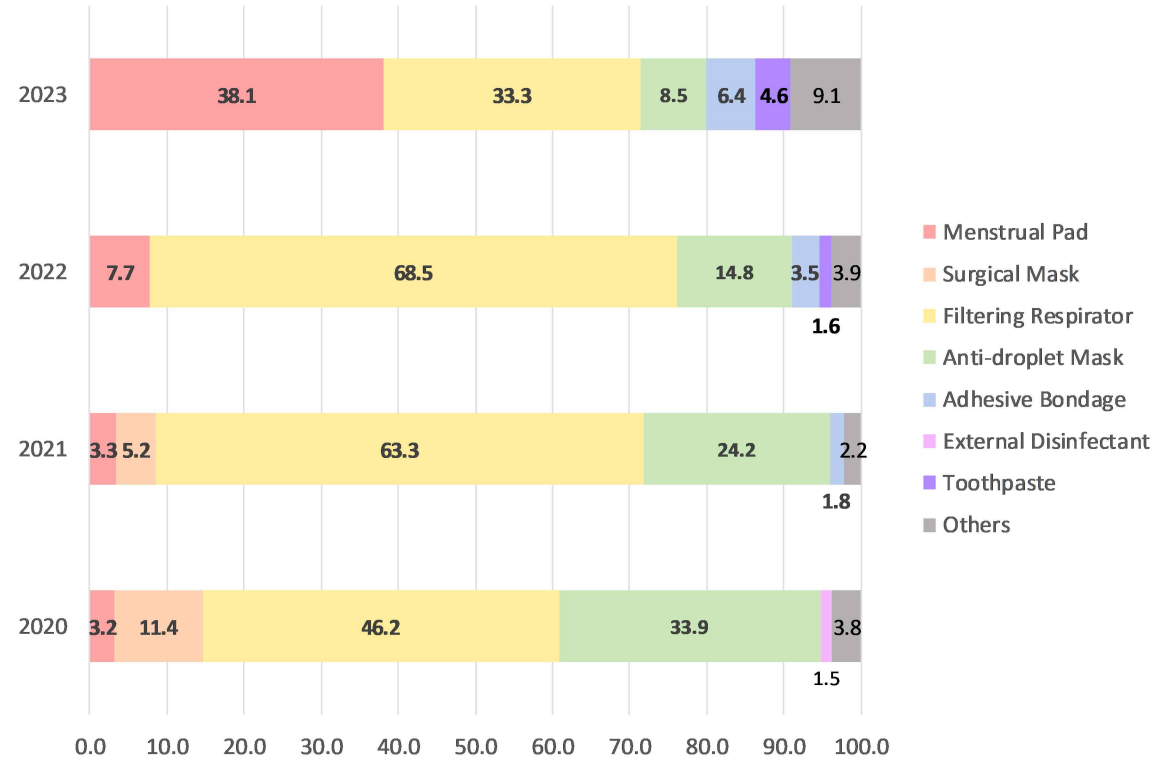


Fig. 3 Percentage of Approval by Year and Quasi-Drug Classification Number ('20~'23)

### 3.2. Changes in Management of Quasi-Drug Approval

The Ministry of Food and Drug has continuously expanded designation of the scope of quasi-drugs and prepared management system to preemptively secure safety of the consumers. To provide the status of domestic approval and notification of quasi-drugs, the Ministry has published approval reports, of which main contents for each year are as follows.

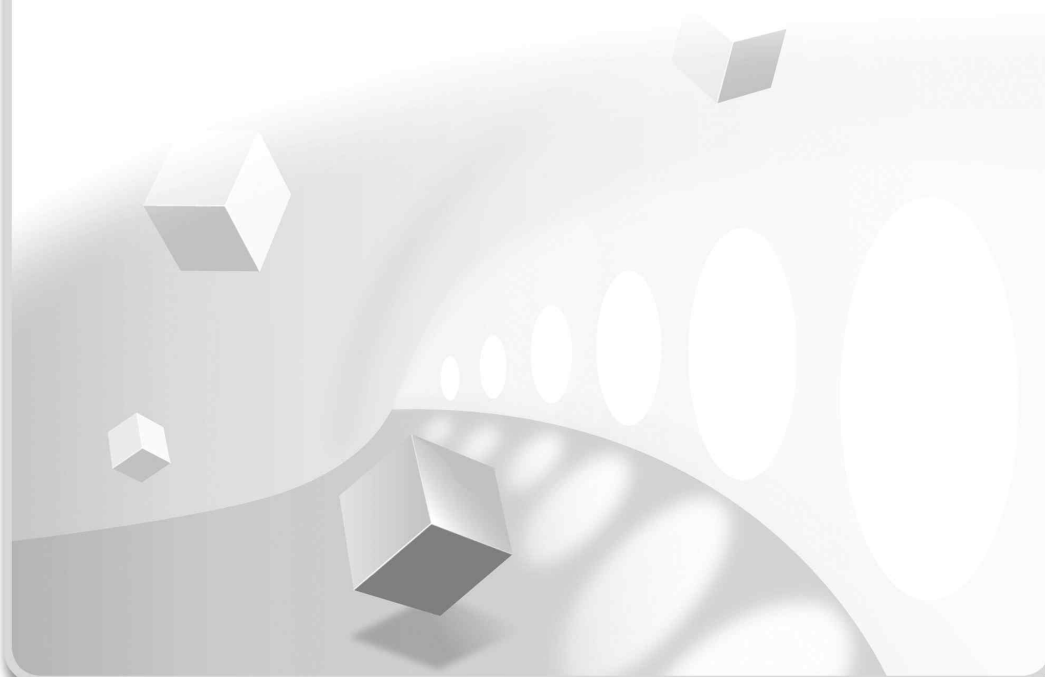
2020	<ul style="list-style-type: none"> <li>• Respond to COVID 19 crisis</li> <li>- Newly establish 'Anti-droplet Mask' as a quasi drug</li> <li>* Revise 'Designation of scope of quasi-drugs' (June 1, 2020)</li> </ul>
2021	<ul style="list-style-type: none"> <li>• Improve quality of personal disinfection products</li> <li>- Prepare standard specifications for mask raw materials (Plastic Nose Wire, Ear Loops)</li> <li>* Establish specification on raw materials in 'Korean Quasi-drug Codex (KQC)' (Feb. 26, 2021)</li> <li>• Prepare for the carbon neutral era</li> <li>- 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)</li> </ul>
2022	<ul style="list-style-type: none"> <li>• Support activation of market entry of quasi-drug mask</li> <li>- Establish standardization of quasi-drug mask of which approval has rapidly increased since the spread of COVID 19.</li> </ul>

	<ul style="list-style-type: none"> <li>* 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).</li> </ul>
<b>2023</b>	<ul style="list-style-type: none"> <li>• Reinforce connection between designation of scope of quasi-drug and classification number</li> <li>- <b>Unify classification system of quasi-drugs similar to Article A and Article B</b></li> <li>* 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)</li> </ul>

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 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 notification: (「Regulation on Safety of Pharmaceuticals」 (Ordinance of the Prime Minister) Paragraph 4, Article 8)

- 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 22 Status of Departments Related to Quasi-Drug Civil Complaints (as of Jun 2024)

Classification	Department	Detailed Petition Service
Biopharmaceuticals and Herbal Medicine Bureau	Biopharmaceutical Approval TF	Quasi-drug manufacturing (import) approval (including change) • Items subject to safety and efficacy review only
	Quasi-drugs Policy Division	• Designation and classification of Quasi-drug • 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 efficacy review • Standards and test method review • 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 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		

## Quasi-Drug Manufacturing (Import) Approval/ Notification Procedure

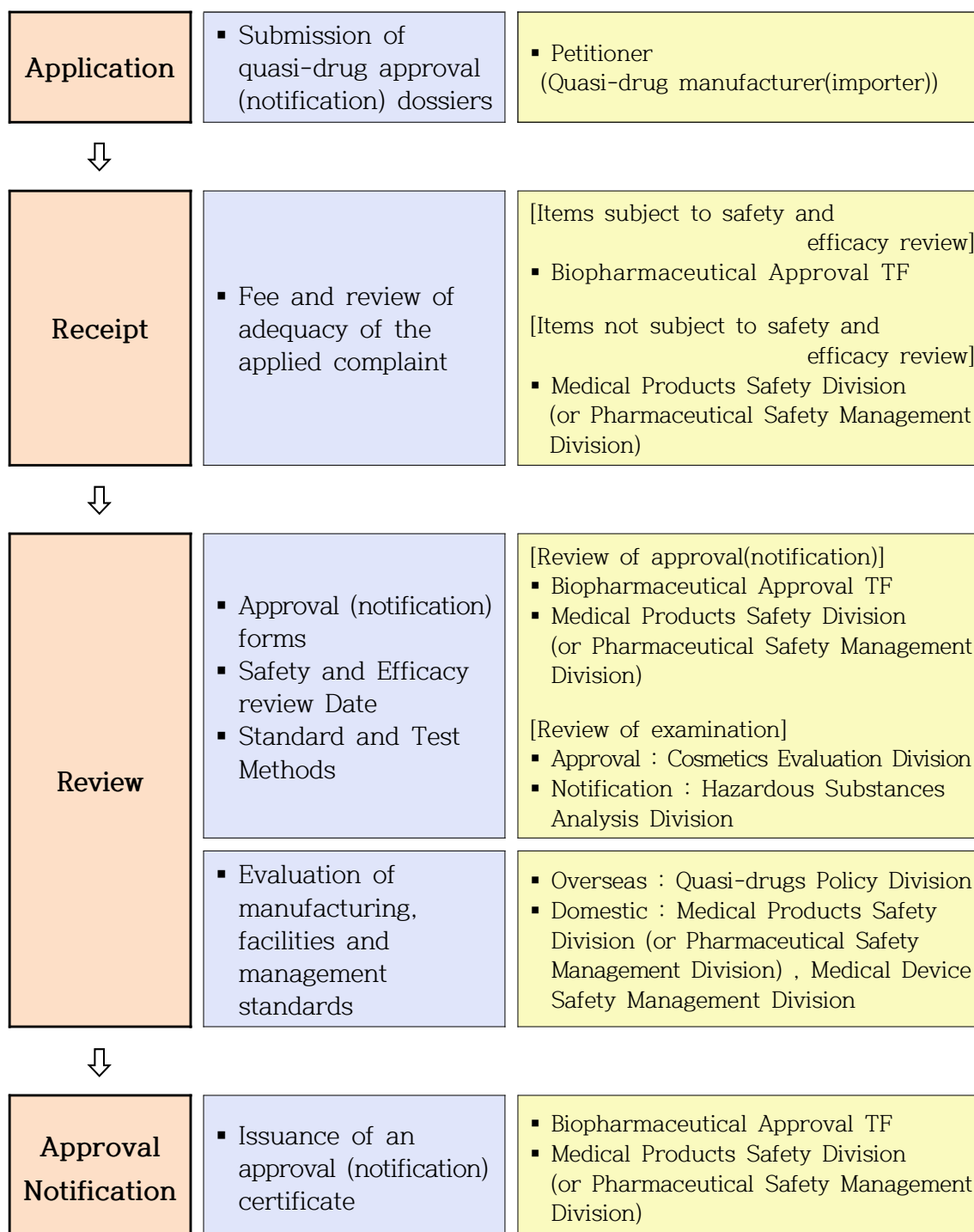


Fig. 4 Quasi-Drug Manufacturing (Import) Approval/ Notification Procedure

## Appendix IV Quasi-Drug Approval/ Notification Status

**Table 23** Quasi-Drug Manufacturing (Import) Approval/ Notification Status by year ('20~'23)

(Unit: Number of Items)

Year	Total	Approval	Notification	Head Office	Regional office	Mfg.	Import
'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%)
'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%)

\* Including cancellation or withdrawal, excluding for export

**Table 24** Approval and Notification Status by Classification Number ('20~'23)

(Unit: Number of Items)

Year	Menstrual Pad [3110]	Filtering Respirator [3220]	Toothpaste [4140]	Anti-droplet Mask [3230]	Bandage [3380]	External Disinfectant [4600]	Surgical Mask [3210]	Mouth Freshener [4110]	Others	Total
'23	313 (33.7%)	220 (23.7%)	150 (16.1%)	65 (7.0%)	62 (6.7%)	28 (3.0%)	21 (2.3%)	19 (2.0%)	51 (5.5%)	929
'22	336 (16.6%)	1,086 (53.5%)	122 (6.0%)	233 (11.5%)	110 (5.4%)	55 (2.7%)	18 (0.9%)	16 (0.8%)	53 (2.6%)	2,029
'21	392 (7.7%)	2,819 (55.6%)	128 (2.5%)	1,076 (21.2%)	188 (3.7%)	147 (2.9%)	232 (4.6%)	19 (0.4%)	66 (1.3%)	5,067
'20	436 (8.9%)	1,651 (33.8%)	204 (4.2%)	1,214 (24.9%)	128 (2.6%)	755 (15.5%)	408 (8.4%)	17 (0.3%)	68 (1.4%)	4,881

## Appendix V Classification of Quasi-Drug Item

### ※ Related Regulations

#### - 'Designation of the scope of quasi-drug'

(Notice of MFDS No. 2020-48, 29. May, 2020)

#### - 'Regulations on Quasi-Drug Classification Numbers'

(Rule of MFDS No. 191, 28. June, 2023)

Table 25 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 (Stokinet)(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) Antiperspirants(For external use only)(4120)	
		3) Heat rash·Skin erosion Treatment Products(4130)	
		4) Toothpaste(4140)	

Item(Classification Number)		Remarks
	<b>C. Repellent for mosquitoes, ticks, etc. applied to the human body for health of human</b>	Repellent(4320)
	<b>D. Contact lens care products</b>	Contact Lens Care Products (4400)
	<b>E. Products that do not contain nicotine, falling under the following criteria</b> (excluding products containing tobacco(leaf tobacco))	1) Smoking Desire Reducer (4510)
		2) Smoking Habit Improvement aids(4520)
	<b>F. External disinfectant directly used on the human body</b> (Active ingredients : hydrogen peroxide, isopropyl alcohol, benzalkonium chloride, cresol and ethanol only)	External Disinfectant(4600)
	<b>G. Ointment, cataplasma agent, External Spray Pas</b> (prescribed by the quasi-drug manufacturing standards)	Ointment(4711)
		Cataplasma Agent(4712)
		External Spray Pas(4713)
	<b>H. Products for internal use</b> (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)
	<b>I. Formulation used for oral hygiene, etc.</b>	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)

Item(Classification Number)			Remarks
		3) Anti-snoring Agent (aid)(4830)	
		4) Teeth Whitener(4840) (containing less than 3% hydrogen peroxide)	
		5) Products used to cleaning or disinfecting denture (false teeth), dental braces, etc.(4850)	
		6) Plaque (tongue plaque) Dyeing (coloring) Agent(4860)	
Group 4	A. Non-adhesive products such as pads, sponges, etc. used for absorbing the exudate, etc. from the affected areas	Non-adhesive products used to absorb exudate of the affected area(3510)	Products similar to Group 1 and 2
	B. Sterilized products such as sterilized cotton swabs, sterilized gloves, etc. used during surgical procedure for prevention of infection	Sterilized products use for surgical treatment for the purpose of infection prevention(3520)	
	C. Wet tissue for oral cleaning to clean teeth and gums	Wet tissue for oral hygiene(3400)	
	D. Products used to temporarily adjust the color of teeth by applying to the surface of teeth	Products used to temporarily adjust the color of teeth by applying to the surface of teeth(4870)	
	E. Portable products used for human inhalation with temporary supply of air or oxygen before and after mountain climbing or exercise	Portable products containing air composition or oxygen intended for human inhalation(4920)	
	F. Products used for hygiene management of bleeding immediately after childbirth and lochia (vaginal discharge after childbirth)(3600)		
	G. Products similar to group 1(3530)		

## 2023 Quasi-Drug Approval Report

Date of Publication	Jun. 2024
Publisher	Oh Yu-Kyoung
Editor in Chief	Shin Joon-Su
Editor	Park Hyunjung, Lee Naery, Cho Hyun-Young
Organization	Biopharmaceutical Approval TF of Biopharmaceuticals and Herbal Medicine Bureau, Ministry of Food and Drug Safety

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