Issuance Registration No.
11-1471000-000562-10

2023 Drug Approval Report

June 2024

Ministry of Food and Drug Safety

Pharmaceutical Approval Management Division

Biopharmaceutical Approval TF

Contents

List of Tables

List of Figures

1

General Status of 2023 Drug Approval and Notification

1. General Status of 2023 Drug Approval and Notification

The 2023 Drug Approval Report is intended to share the status of all the approved and notified drugs organized and analyzed in multiple ways for establishing and executing pertinent policies, streamlining and systematizing approval and notification tasks and boosting the product development, which is in line with the 2022 Drug Approval Report.

1.1. General Status

Table 1 shows all drugs including chemical drugs, biologics and herbal medicinal products which were approved and notified from 2018 to 2023.

In 2023, 1,488 items were approved and notified, 148 items less than the previous year, of which 885 items (59.5%) were approved and 603 items (40.5%) were notified. The number of approved items is 196 items less and that of notified items is 48 items more than 2022.

According to the institution-specific analysis of the total, 585 items (39.3%) were approved by the MFDS and 903 items (60.3%) were approved and notified by the Regional FDS, which indicates that the number of items approved and notified by the MFDS decreased slightly while the number of items approved by the Regional FDS was similar to the last year.

According to the manufactured/imported item category, domestically manufactured and marketed items were 1,337 items (89.9%), whereas imported ones accounted for 151 items (10.1%), indicating that the share of imported items increased slightly since 2019 but the share of domestically manufactured items remains high.

Drug products accounted for 1,300 items (87.4%), drug substances 49 items (3.3%) and medicinal herbs 139 items (9.3%), which are similar to those in the previous year.

The proportion of drug products and drug substances, excluding medicinal herbs, were 96.4% (1,300 items) and 3.6% (49 items), respectively and drug products accounted for 68.0% (884 items) and OTC drugs accounted for 32.0% (416 items) in drug products.

Table 1. Drug Approval and Notification Overview (2018~2023)

(Unit: Number of items)

Year	Total	Approval	Notification	MFDS	Regional FDS	Manufactured	Imported	Drug Product	Drug Substance	Medicinal Herb	Drug Product ETC	Drug Product OTC
2023	1,488	885 (59.5%)	603 (40.5%)	585 (39.3%)	903 (60.7%)	1,337 (89.9%)	151 (10.1%)	1,300 (87.4%)	49 (3.3.%)	139 (9.3%)	884 (68.0%)	416 (32.0%)
		Excluding medicinal herbs (139)		Excluding medicinal herbs (139)		Excluding medicinal herbs (139)		Excluding medicinal herbs (%)				
		885 (65.6%)	464 (34.4%)	585 (43.4%)	764 (56..6%)	1,198 (88.8%)	151 (11.2%)	1,300 (96.4%)	49 (3.6%)			
2022	1,636	1,081 (66.1%)	555 (33.9%)	710 (43.4%)	926 (56.6%)	1,490 (91.1%)	146 (8.9%)	1,451 (88.7%)	76 (4.6%)	109 (6.7%)	1,097 (75.6%)	354 (24.4%)
		Excluding medicinal herbs (109)		Excluding medicinal herbs (109)		Excluding medicinal herbs (109)		Excluding medicinal herbs (%)				
		1,081 (70.8%)	446 (29.2%)	710 (46.5%)	817 (53.5%)	1,381 (90.4%)	146 (9.6%)	1,451 (95.0%)	76 (5.0%)			
2021	2,270	1,514 (66.7%)	756 (33.3%)	499 (22.0%)	1,771 (78.0%)	2,099 (92.5%)	171 (7.5%)	1,992 (87.7%)	83 (3.7%)	195 (8.6%)	1,542 (77.4%)	450 (22.6%)
		Excluding medicinal herbs (195)		Excluding medicinal herbs (195)		Excluding medicinal herbs (195)		Excluding medicinal herbs (%)				
		1,512 (72.9%)	563 (27.1%)	499 (24.0%)	1,576 (76.0%)	1,904 (91.8%)	171 (8.2%)	96.0%	4.0%			
2020	3,496	2,319 (66.3%)	1,177 (33.7%)	738 (21.1%)	2,758 (78.9%)	3,323 (95.1%)	173 (4.9%)	3,229 (92.4%)	69 (2.0%)	198 (5.7%)	2,525 (78.2%)	704 (21.8%)
		Excluding medicinal herbs (198)		Excluding medicinal herbs (198)		Excluding medicinal herbs (198)		Excluding medicinal herbs (%)				
		2,315 (70.2%)	983 (29.8%)	734 (22.3%)	2,564 (77.7%)	3,125 (94.8%)	173 (5.2%)	97.9%	2.1%			
2019	6,187	3,691 (59.7%)	2,496 (40.3%)	629 (10.2%)	5,558 (89.8%)	6,035 (97.5%)	152 (2.5%)	4,809 (77.7%)	71 (1.2%)	1,307 (21.1%)	4,139 (86.1%)	670 (13.9%)
		Excluding medicinal herbs (1307)		Excluding medicinal herbs (1307)		Excluding medicinal herbs (1307)		Excluding medicinal herbs (%)				
		3,684 (75.5%)	1,196 (24.5%)	622 (12.7%)	4,258 (87.3%)	4,728 (96.9%)	152 (3.1%)	98.5%	1.5%			
2018	2,482	1,379 (55.6%)	1,103 (44.4%)	397 (16.0%)	2,085 (84.0%)	2,360 (95.1%)	122 (4.9%)	2,046 (82.4%)	75 (3.0%)	361 (14.6%)	1,514 (74.0%)	532 (26.0%)
		Excluding medicinal herbs (361)		Excluding medicinal herbs (361)		Excluding medicinal herbs (361)		Excluding medicinal herbs (%)				
		1,378 (65.0%)	743 (35.0%)	396 (18.7%)	1,725 (81.3%)	1,999 (94.2%)	122 (5.8%)	96.5%	3.5%			

* Excluding drugs for export (47 items), including revoked and withdrawn items and medicinal herbs

Tables 2-1~2-3 and Figures 1-1~1-2 show the status of the number of items approved and notified annually, which indicates that the number of approved items in 2023 decreased by 18.1% compared to 2022, reaching 885 items.

The notification items increased by 8.6% when including medicinal herbs, and 4% when excluding medicinal herbs than 2022, with notification of 603 items and 464 items, respectively.

In case of medicinal herbs, they were all notified items (139 items) in 2023, which showed a moderate increase (27.5%) from 2022 (109 items).

Table 2-1. Number of Drugs Approved and Notified Annually (Including medicinal herbs)

(Unit: Number of items)

Category	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Approval	1,423	1,811	2,110	2,036	1,315	1,379	3,691	2,319	1,514	1,081	885
(Year-on-year increase, %)	47.3%	16.6%	-3.5%	-35.4%	4.9%	167.7%	-37.2%	-34.7%	-29.9%	-18.1%	
Notification	973	1,296	2,813	1,792	1,209	1,103	2,496	1,177	756	555	603
(Year-on-year increase, %)	33.2%	117.1%	-36.3%	-32.5%	-8.8%	126.3%	-52.8%	-35.8%	-26.6%	8.6%	
Total	2,396	3,107	4,923	3,828	2,524	2,482	6,187	3,496	2,270	1,636	1,488
(Year-on-year increase, %)	29.7%	58.4%	-22.2%	-34.1%	-1.7%	149.3%	-43.5%	-35.1%	-27.9%	-9.0%	

* Excluding drugs for export and medicinal herbs, including revoked·withdrawn items

Table 2-2. Number of Drugs Approved and Notified Annually (Excluding medicinal herbs)

(Unit: Number of items)

Category	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Approval	1,423	1,811	2,110	2,030	1,306	1,378	3,684	2,315	1,512	1,081	885
(Year-on-year increase, %)	27.3%	16.6%	-3.8%	-35.7%	5.5%	167.3%	-37.2%	-34.7%	-29.9%	-18.1%	
Notification	787	1,118	904	815	798	743	1,196	983	563	446	464
(Year-on-year increase, %)	42.1%	-19.1%	-9.8%	-2.1%	-6.9%	61.0%	-17.8%	-42.7%	-20.8%	4.0%	
Total	2,210	2,929	3,014	2,845	2,104	2,121	4,880	3,298	2,075	1,527	1,349
(Year-on-year increase, %)	32.5%	2.9%	-5.6%	-26.0%	8.1%	130.1%	-32.4%	-37.1%	-26.4	-11.7%	

Table 2-3. Number of Medicinal Herbs Notified Annually

(Unit: Number of items)

Category	2013년	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Medicinal herbs	186	178	1,909	983	420	361	1,307	198	195	109	139
(Year-on-year increase, %)	-4.3%	972.5%	-48.5%	-57.3%	-14.0%	262.0%	-85.2%	-1.5%	-44.1%	27.5%	

* Excluding drugs for export, including revoked/withdrawn items

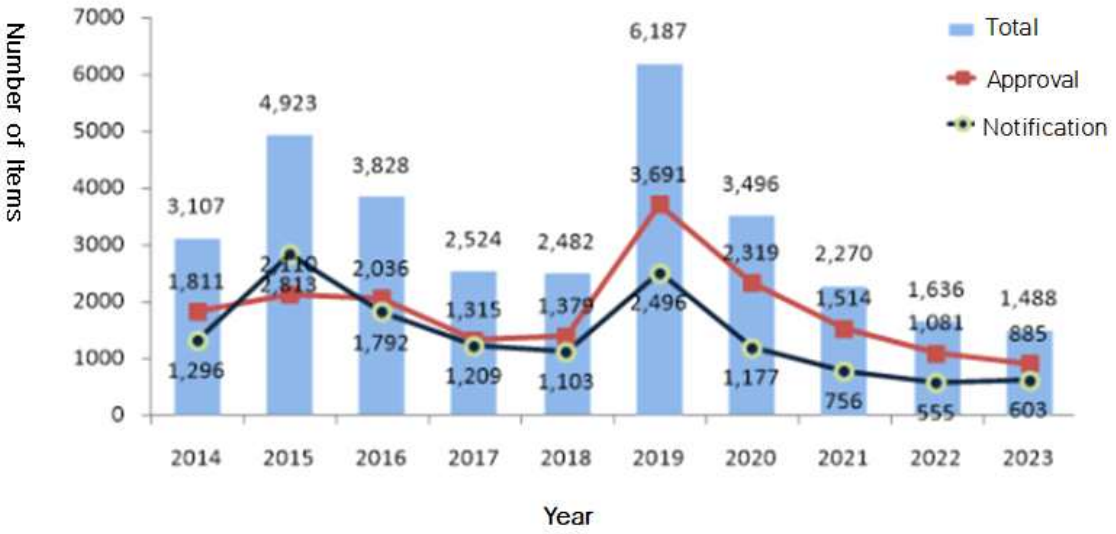

Figure1-1. Number of Approved and Notified Drugs (2014~2023)

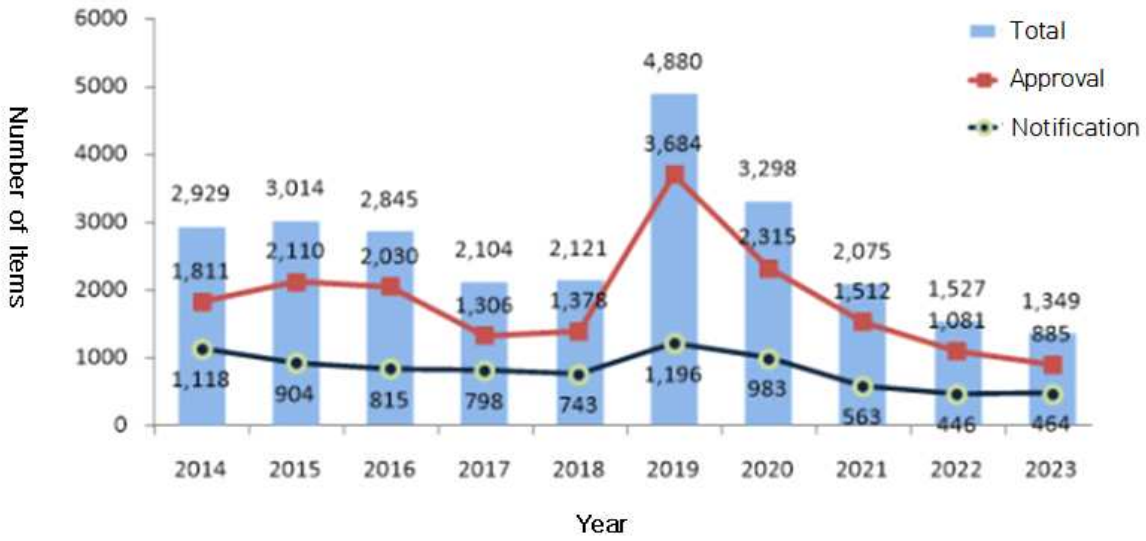

Figure 1-2. Number of Approved and Notified Drugs (2014~2023)
(Excluding Medical Herbs)

The institution-specific analysis (Table 3-1) of the drug approval and notification in 2023 shows that the MFDS approved 585 items (66.1%) while the regional FDS approved 300 items (33.9%) of the total 885 approved items. All notified items and medicinal herbs were approved by regional FDS with 464 items and 139 items respectively (refer to Table 3-1).

Table 3-1. 2023 Drug Approval and Notification by Institution

(Unit: Number of items)

Category	Total	MFDS	Regional FDS
Approval	885 (100%)	585 (66.1%)	300 (33.9%)
Notification	464	0	464
Medicinal Herbs	139	0	139
Total	1,488 (100%)	585 (39.3%)	903 (60.7%)

* Excluding drugs for export (47 items), including revoked and withdrawn items and medicinal herbs

Drug products accounted for 99.5% (1,192 items) and drug substances 0.5% (6 items) of the domestically manufactured items while drug products 71.5% (108 items) and drug substances 28.5%(43 items) 71.5% of the imported items, in which the drug products occupied a larger portion than the drug substance (refer to Table 3-2)

Table 3-2. 2023 Drug Approval and Notification Overview

(Unit: Number of items)

Domestically Manufactured (1,198 items)				Imported (151 items)			
Drug Products **(1,192)** 99.5%	ETC (789) 66.2 %	Approval (766)	MFDS (468)	**Drug** Products **(108)** 71.5%	ETC (95) 88.0 %	Approval (93)	MFDS (92)
			Regional FDS (298)				Regional FDS (1)
		Notification (23)	Regional FDS (23)			Notification (2)	Regional FDS (2)
	OTC (403) 33.8 %	Approval (21)	MFDS (20)		OTC (13) 12.0 %	Approval (2)	MFDS (2)
			Regional FDS (1)				
		Notification (382)	Regional FDS (382)			Notification (11)	Regional FDS (11)
Drug Substances (6) 0.5%		Approval (1)	MFDS (1)	**Drug Substances (43)** 28.5%		Approval (2)	MFDS (2)
		Notification (5)	Regional FDS (5)			Notification (41)	Regional FDS (41)

* Excluding drugs for export (47 items) and medicinal herbs (139 items), including revoked and withdrawn items

According to the Regional FDS-specific analysis of the approval and notification, the three regions accounting for the majority (86.0%) were Gyeongin FDS, Daejeon FDS and Seoul FDS with the rate of 42.6%(385 items), 25.1%(227 items) and 18.3%(165 items) respectively. For medicinal herbs notification, Seoul FDS accounted for 42.4%(59 items), Gyeongin FDS accounted for 35.3% (49 items) and Gwangju FDS accounted for 15.1% (21 items) (refer to Table 4).

Table 4. Details of 2023 Drug Approval and Notification by Regional FDS

(Unit: Number of items)

Category		Approval	Notification	Medicinal Herbs	Total
Regional FDS	Gyeongin	160 (53.3%)	176 (37.9%)	49 (35.3%)	385 (42.6%)
	Daejeon	89 (29.7%)	138 (29.7%)	0 (0.0%)	227 (25.1%)
	Daegu	5 (1.7%)	20 (4.3%)	10 (7.2%)	35 (3.9%)
	Gwangju	6 (2.0%)	41 (8.8%)	21 (15.1%)	68 (7.5%)
	Seoul	35 (11.7%)	71 (15.3%)	59 (42.4%)	165 (18.3%)
	Busan	5 (1.7%)	18 (3.9%)	0 (0%)	23 (2.5%)
Total		300 (100%)	464 (100%)	139 (100%)	903 (100%)

* Excluding drugs for export (47 items), including revoked and withdrawn items and medicinal herbs

Regarding the approval and notification of manufactured and imported items, the approval items took the higher proportion than the notified items. In the case of manufactured items, the approved items (58.9%) were more than the notified items (41.1%) by 17.8%. For imported items, the proportion of approved items (64.2%) were more than double that of notified items (35.8%) (refer to Table 5).

Table 5. Manufactured and Imported Drugs Approved in 2023

(Unit: Number of items)

Category	Total	Manufactured	Imported
Approval	885	788 (58.9%)	97 (64.2%)
Notification	603	549 (41.1%)	54 (35.8%)
Total	1,488	1,337 (100%)	151 (100%)

* Excluding drugs for export (47 items), including revoked and withdrawn items and medicinal herbs

For the approval and notification for drug products and drug substances, in the case of drug products, approved items accounted for 67.8% (882 items) and notified items accounted for 32.2% (418 items). In the case of drug substances (excluding medicinal herbs), approved items accounted for 6.1% (3 items) and notified items accounted for 93.9% (46 items). The approved items accounted for the most of the drug products and the notified items accounted for the most of the drug substances (refer to Table 6).

Table 6. Details of Drug Products and Substances Approved and Notified in 2023

(Unit: Number of items)

Category	Total	Drug Product	Drug Substance (Including medicinal herbs)	Drug Substance (Excluding medicinal herbs)
Approval	885	882 (67.8%)	3 (1.6%)	3 (6.1%)
Notification	603	418 (32.2%)	185 (98.4%)	46 (93.9%)
Total	1,488	1,300 (100%)	188 (100%)	49 (100%)

* Excluding drugs for export (47 items), including revoked/withdrawn items
* Drug substances subject to DMF registration are excluded as they are not subject to approval/notification and are managed through registration

According to the analysis by type of drug products (approved and notified items), chemical drugs accounted for the majority at 91.7% (1,192 items), followed by herbal medicinal products took up 4.4% (57 items), biologics 3.8% (50 items) and advanced biological products at 0.1% (1 items) (refer to Table 7).

Table 7. Classification of Chemical Drugs, Biologics, Advanced Biological Products and Herbal Medicinal Products within Drug Products in 2023

(Unit: Number of items)

Category	Total[1]	Chemical Drugs[2]	Biologics[3]	Advanced Biological Products[4]	Herbal Medicinal Products[5]
Drug Product	1,300	1,192 (91.7%)	50 (3.8%)	1 (0.1%)	57 (4.4%)

1) Excluding drugs for export (47 items), including revoked/withdrawn items
2) Out of 1,192 items, 521 items were approved by the MFDS
3) All items were approved by the MFDS (Excluding Advanced Biological Products)
4) All items were approved by the MFDS
5) Out of 57 items, 10 items were approved by the MFDS

Regarding drug products approved and notified by review type, new drugs (including new orphan drugs) accounted for 2.7% (35 items), drugs requiring data submission (including incrementally modified drugs) accounted for 32.8% (427 items) and generic drugs accounted for 61.7% (802 items), of which generic drugs accounted for the largest proportion. Among drugs requiring data submission, 15 chemical drugs were certified as incrementally modified drugs (IMDs) (refer to Table 8).

Table 8. Classification of Drug Products by Review Type in 2023

(Unit: Number of items)

Cate-gory	Type (Total)	New drugs		Orphan drugs	Drugs that require data submission		Others	
		New drugs	New orphan drugs	Orphan drugs	IMDs	Drugs that require data submission	(MFDS)	(Regional FDS)
Drug pro-ducts	Chemical drugs 1,192	28	-	22	15	375	81[4]	671[5]
	Biologics 50[6]	6	2	12	-	30	-	-
	Advanced biological products 1	-	-	1	-	-	-	-
	Herbal (oriental) medicines 57	-	-	-	-	7	3	47
Total	1,300[1] (100%)	34	2[3]	35 (2.7%)	15	412	84	718
		36[2] (2.8%)			427 (32.8%)		802 (61.7%)	

1) Excluding drugs for export (47 items), including revoked/withdrawn items
2) 34 items were approved as new drugs in 2023, excluding designated new drugs (1 item) throughpost-approval changes including revocation from the orphan drug list (refer to Table 15)
3) New drug substances designated as both orphan drug and new drug (designated by re-review)
4) Special dosage form, generic narcotic drugs, and items exempt from review about safety and efficacy, etc
5) Items within the standard manufacturing criteria, generic items, etc
6) Excluding drugs for export and advanced biological products

In addition, majority of the drug products approved by the MFDS were chemical drugs (521 items, 89.5%) followed by biologics (50 items, 8.6%) and herbal medicinal products (10 items, 1.7%) and advanced biological products (1 item, 0.2%). Medicinal products and herbal medicinal products were mostly approved as manufactured items, but in the case of biologics, the number of approved imported items (38 items) was higher than manufactured items (12 items) by more than 3 times (refer to Table 9).

Table 9. Detailed Status of Drug Product Approval (by the MFDS) in 2023

(Unit: Number of items)

Type	Total	Manufactured	Imported
Approved by the MFDS (drug products)	582	488	94
Drugs (including narcotics)	521 (89.5%)	466	55
Biologics	50 (8.6%)	12	38
Advanced biological products	1 (0.2%)	0	1
Herbal (oriental) medicines	10 (1.7%)	10	0

* Excluding drugs for export, including revoked/withdrawn items

According to the approval of ETC drugs and OTC drugs among drug products, ETC drugs were 68.0% (884 items), which was two times more than OTC drugs (32.0%, 416 items). In addition, the number of approved drug products (882 items) was approximately two times higher than that of notified items (418 items) (refer to Table 10).

Table 10. Detailed Overview of 2023 Drug Product Approval

(Unit: Number of items)

Category	Total	ETC	OTC
Total	1,300 (100%)	884 (68.0%)	416 (32.0%)
Approval	882 (100%)	859 (97.4%)	23 (2.6%)
Notification	418 (100%)	25 (6.0%)	393 (94.0%)

* Excluding drugs for export (47 items) and medicinal herbs (139 items), including revoked and withdrawn items

The anlysis of the annual trends of each drug type approved and notified shows that the number of approved and notified items by drug type was similar in 2017 and 2018, but in 2019, the number (6,187 items) increased by around 2.5 times that in 2018. However, the number of approved and notified ETC, OTC and medicinal herbs decreased again since 2020 but that of OTC and medicinal herbs increased in 2023.

Specifically, 884 ETC drugs, 416 OTC drugs, 49 drug substances and 139 medicinal herbs were approved in 2023, in which the number of approved ETC drugs and drug substances decreased by 19.6%(1,097 items), 35.5%(76 items) respectively and that of approved OTC drugs and medicinal herbs increased by 17.5%(354 items), 27.5%(109 items) respectively compared to 2022.

Table 11. Number of Approvals and Notifications by Drug Type (2014~2023)

(including revoked·withdrawn items)

(Unit: Number of items)

Category	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
ETC Drugs	2,090	2,289	2,280	1,573	1,514	4,139	2,525	1,542	1,097	884
(Year-on-year Increase %)	9.5%	-0.4%	-31.0%	-3.8%	173.4%	-39.0%	-38.9%	-28.9%	-19.6%	
OTC Drugs	726	626	481	476	532	670	704	450	354	416
(Year-on-year Increase %)	-13.8%	-23.2%	-1.0%	11.8%	25.9%	5.1%	-36.1%	-21.3%	17.5%	
Drug Substances	113	99	84	55	75	71	69	83	76	49
(Year-on-year Increase %)	-12.4%	-15.2%	-34.5%	36.4%	-5.3%	-2.8%	20.3%	-8.4%	-35.5%	
Medicinal Herbs	178	1,909	983	420	361	1,307	198	195	109	139
(Year-on-year Increase %)	972.5%	-48.5%	-57.3%	-14.0%	262.0%	-84.9%	-1.5%	-27.9%	27.5%	
Total	3,107	4,923	3,828	2,524	2,482	6,187	3,496	2,270	1,636	1,488

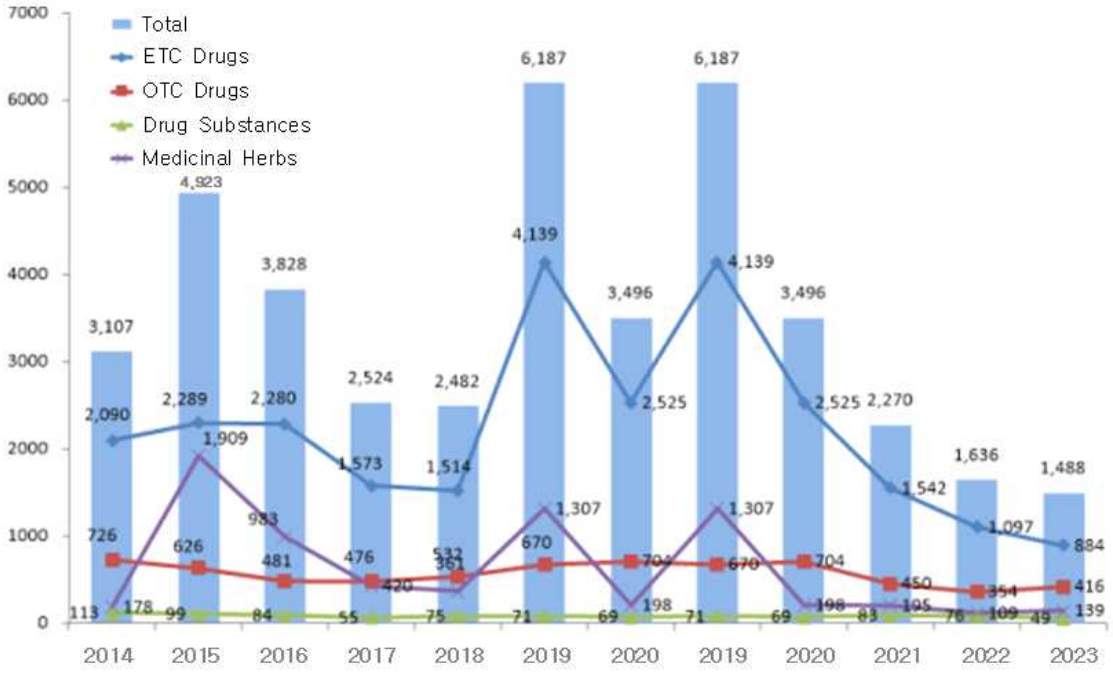

Figure 2. Approval and Notification Status by Drug Type (2014~ 2023)

The number of post-approval changes approved and notified annually increased in 2020, 9,028 increase from 2019 (25,874 vs 16,846, respectively) but has been on the decline thereafter, in 2023, that of post-approval changes dropped to 2019 level(16,482). The number of post-approval changes in biologics increased in 2020 (289) compared to 2019 but it has shown decreasing trend since 2021. The number of changes for herbal medicinal products and medicinal herbs was 1,229 and 1,423, respectively in 2023, indicating the highest number of changes for the previous five years. For advanced biological products, post-approval changes have been made since 2021, but the number of which is low. The analysis of the number of approved and notified post-approval changes in 2023 by drug category showed that the medicinal products accounted for the highest share (82.3%) followed by

medicinal herbs (7.1%), herbal medicinal products (6.1%), biologics (4.3%), advanced biological products (0.1%) (refer to Table 12-1).

Table 12-1. Details of Approved (Notified) Post-Approval Changes in Drug Products between 2019 and 2023

Type		2019	2020	2021	2022	2023
Medicinal Products	Total	16,846 (91.2%)	25,874 (89.8%)	25,163 (93.3%)	22,879 (92.2%)	16,482 (82.3%)
	Minor Changes	2,836 (95.7%)	5,566 (90.5%)	2,610 (95.5%)	3,011 (97.5%)	3,140 (85.4%)
Biologics	Total	693 (3.8%)	982 (3.4%)	888 (3.3%)	928 (3.7%)	871 (4.3%)
	Minor Changes	58 (2.0%)	84 (1.3%)	45 (1.6%)	32 (1.0%)	24 (0.7%)
Advanced Biological Products	Total	-	-	13 (0.0%)	26 (0.1%)	24 (0.1%)
Herbaal Medicinal Products	Total	402 (2.1%)	823 (2.9%)	592 (2.2%)	718 (2.9%)	1,229 (6.1%)
	Minor Changes	68 (2.3%)	143 (2.3%)	74 (2.7%)	39 (1.3%)	477 (13.0%)
Medicinal Herbs	Total	528 (2.9%)	1,135 (3.9%)	304 (1.1%)	251 (1.0%)	1,423 (7.1%)
	Minor Changes	1 (0.0%)	356 (5.7%)	5 (0.2%)	5 (0.2%)	35 (1.0%)
Total	Total	18,469 (100%)	28,814 (100%)	26,960 (100%)	24,802 (100%)	20,029 (100%)
	Minor Changes	2,963 (100%)	6,149 (100%)	2,734 (100%)	3,087 (100%)	3,676 (100%)

* Including narcotics, excluding voluntarily revoked and returned cases

Upon comparing the number of approved and notified post-approval changes, in 2019 and 2020 the number of notified cases (10,140 vs 15,116, respectively) was higher than approved cases (8,329 vs 13,698, respectively) but the number of approved cases was higher than that of notified cases since 2021. In 2023, the number of approved post-approval changes (10,207) was similar to that of notified post-approval

changes (9,822) (refer to Table 12-2).

Table 12-2. Status of Drug Products by Post-Approval Changes Approval and Notification between 2019 and 2023

(Unit: Number of items)

Category	2019	2020	2021	2022	2023
Post-approval changes approval	8,329	13,698	14,345	13,792	10,207
Post-approval changes notification	10,140	15,116	12,615	11,010	9,822
Total	18,469	28,814	26,960	24,802	20,029

For the drug substance listed in DMF, the number of registrations increased from 2019 to 2021, but decreased since 2022, and in 2023, 487 drug substances were registered, down 27.4% from 673 in 2022. Of these, imported drug substances accounted for about 90% of the total, while domestically manufactured drug substances accounted for about 10%, showing a higher proportion of imported drug substances (refer to Table 13).

Table 13. Status of Registration of Drug Master File (DMF) between 2019 and 2023

Category	2019		2020		2021		2022		2023	
Registration	600		730		1,013		673		488	
	Manu-factured	Imported	Manu-factured	Imported	Manu-factured	Imported	Manu-factured	Imported	Manu-factured	Imported
	72 (12.0%)	528 (88.0%)	97 (13.3%)	633 (86.7%)	111 (11.0%)	902 (89.0%)	81 (12.0%)	592 (88.0%)	48 (9.8%)	440 (90.2%)

The number of DMF amendments continued to increased continuously since 2019, the figure of which was 3,469 in 2023, 11.7% increase from

from 3,106 in 2022. Among them, the number of minor changes showed decreasing tendency after 2019 while the number of minor changes but rebounded to 1,510, in 2023, 84 increase from 2022, but the share of the minor changes decreased to 43.5% in 2023, 2.4% down from 45.9% in 2022 (refer to Table 14).

Table 14. Status of Drug Master File(DMF) amendment between 2019 and 2023

Category		2019	2020	2021	2022	2023
amendment	Total	1,966	2,357	2,896	3,106	3,469
	Minor changes	1,363 (69.3%)	1,292 (54.8%)	1,624 (56.1%)	1,426 (45.9%)	1,510 (43.5%)

1.2. Approval of New Drugs

New drugs approved and designated in 2023 were 37 items in total including 29 chemical drugs (5 manufactured items and 24 imported items) and 8 biologics (8 imported) and there were no approved new drugs as advanced biological products and herbal medicinal products. New drugs containing 20 new drug ingredients were approved, which are composed of 13 ingredients from chemical drugs and 7 ingredients from biologics. Compared to domestically manufactured new drugs (5 items, 1 ingredient), the number of approved items and ingredients of imported new drugs (32 items, 19 ingredients) accounted for larger share, indicating that most of the new substances were from imported new drugs (Table 15, refer to Table 18 for the full list of new drugs).

Table 15. New Drugs Approved in 2023

(Unit: Number of items)

Category	Total [Number of Ingredients]	Chemical Drugs	Biologics	Advanced Biological Products	Herbal Medicinal Products
Total	37[1] (100.0%) [20 (100.0%)]	29[2] [13]	8 [7]	0 [0]	0 [0]
Manufactured	5 (13.5%) [1 (5.0%)]	5 [1]	0 [0]	0 [0]	0 [0]
Imported	32 (86.5%) [19 (95.0%)]	24 [12]	8 [7]	0 [0]	0 [0]

1) Out of 37 items, 2 items were designated as both orphan and new drug.

2) In 2023, 28 items of chemical drugs were newly approved and 1 item was designated as new drug as per post-approval changes approval (refer to Table 18)

Comparing the new drug approvals by year, the number of new drugs (37 items) approved in 2023 increased from that of approved items (30 items) in 2022. The number of manufactured biologics decreased by 2 items and that of new imported chemical drugs increased by 9 items from the previous year, showing that the new imported chemical drugs in 2023 are attributed to the total new drug approvals. 86.5% of new drugs were imported items, higher than the previous year (76.7%), showing that the majority of new drugs were still imported.

According to the new drug approval status by year, 1-2 items of domestically developed new drugs were consistently approved per year (5 items in 2015 and 2021) but there was no items developed domestically in 2023 (refer to Table 16-1, Table 16-2 and Figure 3).

Table 16-1. New Drugs Approved Annually (2012~2023)

(Including revoked and withdrawn items)

(Unit: Number of items)

Category	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Manufactured	3 (17.6%)	3 (13.0%)	3 (6.1%)	6 (17.6%)	2 (8.0%)	2 (6.9%)	2 (13.3%)	4 (11.4%)	5 (12.5%)	8 (21.6%)	7 (23.3%)	5 (13.5%)
Imported	14 (82.4%)	20 (87.0%)	46 (93.9%)	28 (82.4%)	23 (92.0%)	27 (93.1%)	13 (86.7%)	31 (88.6%)	35 (87.5%)	29 (78.4%)	23 (76.7%)	32 (86.5%)
No. of items	17	23	49	34	25	29	15	35	40	37	30	37

Table 16-2. Approval of Chemical Drugs, Biologics, Advanced Pharmaceutical Products and Herbal Medicinal Products as New Drugs Annually (2012~2023)

(including revoked · withdrawn items)

(Unit: Number of items)

Category		2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Number of approved items[1)] (Number of new drug ingredients)		17 (14)	23 (15)	49 (27)	34 (19)	25 (10)	29 (18)	15 (12)	35 (21)	40 (20)	37 (28)	30 (22)	37 (20)
Chemical drugs	Domestically developed	2	1	1	5	1	1	2	0	0	2	1	0
	Manufactured	3	3	3	6	2	1	2	4	5	4	5	5
	Imported	10	13	38	18	19	16	9	24	29	19	15	24
Biologics	Domestically developed	0	0	0	0	0	1	0	0	0	2	1	0
	Manufactured	0	0	0	0	0	1	0	0	0	3	2	0
	Imported	4	6	8	10	4	11	4	7	6	8	8	8
Advanced Biological products	Domestically developed	-	-	-	-	-	-	-	-	-	0	0	0
	Manufactured	-	-	-	-	-	-	-	-	-	0	0	0
	Imported	-	-	-	-	-	-	-	-	-	2	0	0
Herbal (oriental) medicines	Domestically developed	0	0	0	0	0	0	0	0	0	1	0	0
	Manufactured	0	0	0	0	0	0	0	0	0	1	0	0
	Imported	0	1	0	0	0	0	0	0	0	0	0	0

1) The number of new drugs with post-approval changes approval (including 1 chemical drugs), the number of newly approved new drugs for the pertinent year

2) The number of manufactured and marketed items includes new drugs developed in Korea

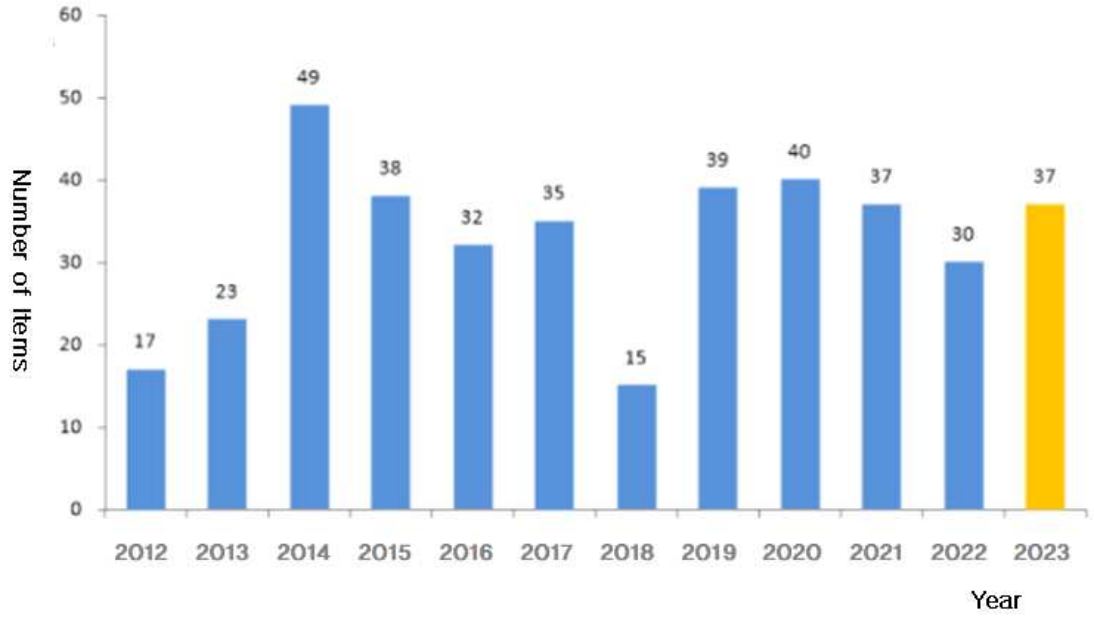

Figure 3. Number of Drugs Approved Annually (2012~2023)

(Including revoked, withdrawn, post-approval changed items) [Refer to Table 15]

Regarding the new drug approval status since 2012 by therapeutic class, 6 items (4 ingredients) of anti-tumor agents in 2012, 6 items (3 ingredients) of anti-diabetes agents in 2013, 16 items (5 ingredients) of nervous system drugs in 2014, 8 items (3 ingredients) of nervous system drugs in 2015, 14 items (7 ingredients) of anti-tumor agents in 2016, 11 items (5 ingredients) of anti-tumor agents in 2017, and 4 items (2 ingredients) of chemotherapeutic agents in 2018 accounted for the majority. From 2019 to 2022, anti-tumor agents accounted for the majority with 13 items (5 ingredients) in 2019, 13 items (6 ingredients) in 2020, 6 items (6 ingredients) in 2021 and 6 items (5 ingredients) in 2022 approved, respectively. In 2023, anti-tumor agents accounted for the highest proportion with 7 items (5 ingredients) and the cumulative number of new drug approvals over the past 12 years could be arranged in descending order: anti-tumor agents (94 items), nervous system drugs (61 items) and anti-diabetes agents (36 items), chemotherapeutic

agents (30 items) and anti-allergic drugs (30 items) and circulatory system drugs (29 items) (refer to Table 17).

Table 17. Therapeutic Class of New Drug Approved Annually (2012~2023)

(Including revoked, withdrawn and post-approval changed items)

(Unit: Number of items)

Category	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023		Total
												Approval	Post-approval change	
Nervous system	1	1	16	8	2	0	0	9	9	6	2	7	0	61
anti-tumor agents	6	4	7	5	14	11	1	13	13	6	6	7	1	94
Anti-diabetes	1	6	11	8	0	0	2	0	0	0	2	6	0	36
Chemothera-peutic agents	1	0	2	5	2	3	4	4	5	0	4	1	0	31
Circulatory system	0	0	1	2	6	9	1	0	3	4	2	1	0	29
Respiratory system	0	0	4	1	2	1	0	1	0	2	0	2	0	13
Genitourinary system	0	2	0	0	0	0	0	0	0	0	1	0	0	3
Sensory system	2	0	3	0	0	0	0	3	0	1	0	1	0	10
Anti-allergic	2	3	1	0	0	8	2	1	3	3	2	5	0	30
Others	4	7	4	9	6	3	5	8	7	16	11	6	0	86
Total	**17**	**23**	**49**	**38**	**32**	**35**	**15**	**39**	**40**	**37**	**30**	**36**	**1**	**393**
												37		

Table 18 List of New Drugs Approved in 2023

(Including items designated as new drugs as per post-approval changes)

☐ Chemical drugs, ☐ Biologics

No.	Manufacturered/ Imported	Product Name	Company	Date of Approval (Designation)	Main ingredient	Efficacy/Effectiveness (partially omitted)
1	Imported	Brukinsa capsules 80mg (Zanubrutinib)	BeiGene Korea	Initial Approval Date 2022-02-24 (Revoked from orphan drug list, switched as new drug on 2023-07-10)	Zanubrutinib	**Mantle Cell Lymphoma(MCL)** Monotherapy in adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy **Waldenstrom Macroglobulin -emia(WM)** Monotherapy in adult patients with Waldenström macroglobulin -emia(WM) who have received at least one prior therapy **Marginal Zone Lymphoma (MZL)** Monotherapy in adult patients with relapsed/refractory marginal zone lymphoma (MZL) who have received at least one prior therapy **Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)** Monotherapy in treatment-naive adult patients with chronic lymphocytic leukemia(CLL) or small lymphocytic lymphoma (SLL) who are either 65 years or older, or under 65 years with comorbidities Monotherapy in adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lym phoma(SLL) who have received at least one prior therapy.

No.	Manufacturered/ Imported	Product Name	Company	Date of Approval (Designation)	Main ingredient	Efficacy/Effectiveness (partially omitted)
2	Imported	Bosulif Tablet 100mg (Bosutinib Monohydrate)	Pfizer Pharma-ceuticals Korea Limited	2023-01-12	Bosutinib Monohydrate	This drug is used for the treatment of the following adult patients: 1. Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML). 2.. Philadelphia chromosome - positive chronic myeloid leukemia(Ph+ CML) in chronic phase(CP), accelerated phase (AP), or blast phase (BP) who are resistant or intolerant to prior therapy
3	Imported	Bosulif Tablet 400mg (Bosutinib Monohydrate)				
4	Imported	Bosulif Tablet 500mg (Bosutinib Monohydrate)				
5	Imported	Vabysmo IVT (faricimab)	Roche Korea Co., Ltd.	2023-01-20	Faricimab	Treatment of neovascular(wet) age-related macular degeneration Treatment of vision loss due to diabetic macular edema
6	Imported	RHOPRESSA ophthalmic solution 0.02% (Netarsudil Mesylate)	Santen Pharma-ceutical Korea Co., Ltd.	2023-02-03	Netarsudil Mesylate	Lowering of intraocular pressure for following diseases Open angle glaucoma, ocular hypertension
7	Imported	Zeposia Capsule 0.92mg (Ozanimod Hydrochloride)	BMS Pharma-ceutical Korea Ltd.	2023-02-23	Ozanimod Hydrochloride	Treatment of moderate to severe active ulcerative colitis in adults who have not responded adequately to, lost response to, or are intolerant of conventional therapies (such as corticosteroids and immunosuppressive agents) or biologics
8	Imported	Zeposia Starter Pack 0.23mg/0.46mg(Ozanimod Hydrochloride)				
9	Imported	Vadanem tablets 150mg (Vadadustat)	Mitsubishi Tanabe Pharma Korea Co., Ltd.	2023-03-13	Vadadustat	Treatment of anemia in adult patients with chronic kidney disease on hemodialysis
10	Imported	Vadanem tablets 300mg (Vadadustat)				
11	Imported	Imjudo injection (tremelimumab)	AstraZeneca Korea	2023-06-23	Tremelimumab	Combination therapy with durvalumab as first-line treatment for adult patients with advanced or unresectable hepatocellular carcinoma

No.	Manufacturered/ Imported	Product Name	Company	Date of Approval (Designation)	Main ingredient	Efficacy/Effectiveness (partially omitted)
12	Imported	Mounjaro Prefilled Pen Inj. 2.5mg/0.5mL (Tirzepatide)	Lilly Korea Ltd.	2023-06-28	Tirzepatide	This is administered as an adjunct to diet and exercise therapy to improve glycemic control in adults with type 2 diabetes. - Monotherapy - Combination Therapy
13	Imported	Mounjaro Prefilled Pen Inj. 5mg/0.5mL (Tirzepatide)				
14	Imported	Mounjaro Prefilled Pen Inj. 7mg/0.5mL (Tirzepatide)				
15	Imported	Mounjaro Prefilled Pen Inj. 10mg/0.5mL (Tirzepatide)				
16	Imported	Mounjaro Prefilled Pen Inj. 12.5mg/0.5mL (Tirzepatide)				
17	Imported	Mounjaro Prefilled Pen Inj. 15mg/0.5mL (Tirzepatide)				
18	Imported	Enjaymo injection (Sutimlimab)	SANOFI-AVENTIS KOREA CO., LTD.	2023-07-12	Sutimlimab	Treatment of hemolysis in adult patients with cold agglutinin disease
19	Imported	PAXLOVID Tablets(nirmatrelvir/ritonavir)	Pfizer Pharma-ceuticals Korea Limited	2023-07-14	Ritonavir, Nirmatrelvir	Mild and moderate Coronavirus Disease 19 (COVID-19) in adults with higher risk of progression to severe COVID-19 including hospitalization or death <Limitation of use> This drug is not approved for pre- or post-exposure prophylaxis of COVID-19
20	Imported	Sotyktu Tablets 6 mg (Deucravacitinib)	BMS Pharma-ceutical Korea Ltd.	2023-08-03	Deucravacitinib	Treatment of moderate-to-severe plaque psoriasis in adult patients with phototherapy or systemic therapy
21	Imported	Spevigo (Spesolimab)	Boehringer Ingelheim Korea	2023-08-09	Spesolimab	Treatment of rapid exacerbations in adult patients with systemic pustular psoriasis

No.	Manufacturered/ Imported	Product Name	Company	Date of Approval (Designation)	Main ingredient	Efficacy/Effectiveness (partially omitted)
22	Imported	Adtralza 150mg (Tralokinumab)	LEO Pharma	2023-08-31	Tralokinumab	Treatment of moderate to severe atopic dermatitis in adults (18 years of age and older) and adolescents (12 to 17 years of age) who are candidates for systemic therapy that is not adequately controlled with topical therapies or for whom these therapies are not recommended
23	Imported	AQUIPTA 10mg tablets (Atogepant)	AbbVie Korea Ltd.	2023-11-15	Atogepant Monohydrate	Prevention of migraines in adults
24	Imported	AQUIPTA 60mg tablets (Atogepant)				
25	Imported	Orkedia Tablets 1 mg (Evocalcet)	Kyowa Kirin Korea Co., Ltd	2023-11-15	Evocalcet	Treatment of secondary hyper-parathyroidism associated with chronic kidney failure patients on dialysis
26	Imported	Orkedia Tablets 2 mg (Evocalcet)				
27	Imported	Tevimbra inj. 100mg (Tislelizumab)	BeiGene Korea	2023-11-20	Tislelizumab	Esophageal squamous cell carcinoma (ESCC) Monotherapy in adult patients with unresectable, recurrent, locally advanced, or metastatic esophageal squamous cell carcinoma who are unable to continue prior platinum-based chemotherapy or who have relapsed or progressed since its administration
28	Manufactured	LATUDA 120mg tablets (Lurasidone Hydrochloride)	BUKWANG PHARM. CO., LTD.	2023-11-23	Lurasidone Hydrochloride	1. Schizophrenia in adolescents and adults 13 years of age and older 2. Major depressive episode associated with bipolar disorder type 1 in pediatric patients who are the age of 10 and older and adult patients.
29	Manufactured	LATUDA 20mg tablets (Lurasidone Hydrochloride)				
30	Manufactured	LATUDA 40mg tablets (Lurasidone Hydrochloride)				
31	Manufactured	LATUDA 60mg tablets (Lurasidone Hydrochloride)				
32	Manufactured	LATUDA 80mg tablets (Lurasidone Hydrochloride)				

No.	Manufacturered/ Imported	Product Name	Company	Date of Approval (Designation)	Main ingredient	Efficacy/Effectiveness (partially omitted)
33	Imported	Pivlaz injection (Clazosentan disodium)	Idorsia Pharmaceuticals Korea Co.,Ltd.	2023-12-07	Clazosentan disodium	Prevention of cerebral infarction, cerebral ischemic symptoms associated with cerebral vasospasm, and cerebral vasospasm after treatment of aneurysmal subarachnoid hemorrhage Administer this drug to patients with ruptured cerebral aneurysms that have been adequately hemostasized by surgical or endovascular treatment. The decision to administer this medication should be based on the patient's condition, including the severity of the subarachnoid haemorrhage, the amount of clot, and the extent of the cerebral infarction. - Concomitant administration of vasodilators such as nimodipine preparations - WFNS (World Federation of Neurosurgical Surgeon) class V patients - Patients with extensive cerebral infarction - Patients with Fisher classification other than 3* * Localized thrombus or presence of blood >1 mm thick in a layer perpendicular to the CT section (with or without intracere- bral or intraventricular hematoma)
34	Imported	TUKYSA film-coated tablet 50 mg (Tucatinib hemiethanolate)	MSD KOREA Co., Ltd.	2023-12-14	Tucatinib hemiethanolate	Combination therapy with trastuzumab and capecitabine for the treatment of adult patients with HER2-positive, unresectable, locally advanced or metastatic breast cancer who have been previously treated with at least 2 anti-HER2 therapies
35	Imported	TUKYSA film-coated tablet 150 mg (Tucatinib hemiethanolate)				
36	Imported	Tezspire autoinjector (Tezepelumab)	AstraZeneca Korea)	2023-12-21	Tezepelumab	Additional maintenance treatment for severe asthma patients aged 12 and older who are not adequately controlled with conventional treatment
37	Imported	Tezspire pre-filled syringe (Tezepelumab)				

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

Table 19. List of New Drugs Developed in Korea (1999~2023)

(Including withdrawn items)

No.	Product Name	Company	Active Ingredient	Efficacy/ Effectiveness	Remarks
1	Sunpla Injection	SK Chemicals	Heptaplatin	Anticancer drug (gastric cancer)	1999.7.15 (1993.7.20)
2	Easyef Topical Solution	Daewoong Pharmaceuticals	Human epidermal cell growth factor	Diabetic, foot ulcer treatment	2001.5.30 (1997.3.4)
3	Milican Injection	Dong Hwa Pharm.	Holmium nitrate-166	Anticancer drug (hepatic cancer)	2001.7.6 (1997.5.28)
4	Q-ROXIN Tablet	JW Pharmaceutical	Balofloxacin	Antimicrobial drug (antibiotic)	2001.12.17 (1993.5.6)
5	Factive Tablet	LG Chem	Gemifloxacin mesylate	Antimicrobial drug (antibiotic)	2002.12.27 US FDA Approval (2003.4.4)
6	Apitoxin Injection	Guju Pharmaceutical	Dry honey bee poison	Arthritis treatment	2003.5.3 (1999.11.29)
7	Pseudovaccine Injection	HK inno.N corporation	Pseudomonas vaccine dried tablet	Pseudomonas aeruginosa preventive vaccine	2003.5.28 (1995.1.26)
8	Camtobell Inj.	Chong Kun Dang Pharm.	Belotecan	Anticancer drug	2003.10.22
9	Revanex Tablet	Yuhan Corporation	Revaprazan HCl	Anti-ulcer drug	2005.9.15
10	Zydena Tablet	DONG-A ST	Udenafil	Erectile dysfunction treatment	2005.11.29
11	Levovir Cap.	Bukang Pharm Co.,Ltd	Clevudine	Hepatitis B treatment	2006.11.13 (2001.6.13)
12	Pelubi Tablet	Daewon Pharm. Co., Ltd	Pelubiprofen	Osteoarthritis treatment	2007.4.20
13	Mvix Tab	SK Chemicals	Mirodenafil HCl	Erectile dysfunction treatment	2007.7.18
14	NOLTEC Tab.	IL-YANG PHARMACEUTICAL CO., LTD	Ilaprazole	Anti-ulcer drug	2008.10.28
15	Kanarb Tablet	Boryung Co., Ltd. Pharmaceutical	Fimasartan potassium trihydrate	Antihypertensive drug	2010.9.9
16	PYRAMAX Tablet	SHIN POONG PHARM. CO., LTD.	Pyronaridine tetraphosphate/artesunate	Malaria treatment	2011.8.17
17	Zepeed Tab.	JW Pharmaceutical	Avanafil	Erectile dysfunction treatment	2011.8.17
18	SUPECT Caps.	IL-YANG PHARMACEUTICAL CO., LTD	Radotinib HCl	Anticancer drug (leukemia)	2012.1.5
19	Zemiglo Tab.	LG Chem	Gemigliptin tartrate 1.5-hydrate	Antidiabetics	2012.6.27
20	Duvie Tab.	Chong Kun Dang Pharm.	Lobeglitazone sulfate	Antidiabetics	2013.7.4
21	Acelex Capsule	CrystalGenomics, Inc.	Polmacoxib	Osteoarthritis treatment	2015.2.5
22	Zaborlante Tab.	DONGWHA PHARM. CO., LTD.	Zabofloxacin D-aspartate hydrate	Antimicrobial drug (antibiotic)	2015.3.20
23	Sivextro Tablet	DONG-A ST	Tedizolid phosphate	Antimicrobial drug (antibiotic)	2015.4.17

No.	Product Name	Company	Active Ingredient	Efficacy/ Effectiveness	Remarks
24	Sivextro Injection	DONG-A ST	Tedizolid phosphate	Antimicrobial drug (antibiotic)	2015.4.17
25	Suganon Tablet	DONG-A ST	Evogliptin tartrate	Antidiabetics	2015.10.2
26	Olita Tab. 200mg	Hanmi Pharm. Co., Ltd.	Olmutinib dihydrochloride monohydrate	Anticancer drug	2016.5.13
27	BESIVO Tab.	ILDONG PHARMACEUTICAL CO., LTD.	Besifovir dipivoxil maleate	Hepatitis B treatment	2017.5.15
28	Alzavue injection	FutureChem Co., Ltd.	Florapronol (18F) solution	Adjuvant diagnosis of Alzheimer's	2018.2.2
29	K-CAP Tab	HK inno.N corporation	Tegoprazan	Gastroesophageal reflux disease treatment	2018.7.5
30	Leclaza Tab.	YUHAN Coporation	Lazertinib mesylate monohydrate	Anticancer drug	2021.1.18
31	Regkirona Inj.	Celltrion	Regdanvimab	COVID-19 treatment	2021.2.5
32	Rolontis Prefilled Syringe Inj.	Hanmi Pharm. Co., Ltd.	Eflapegrastim	Neutropenia	2021.3.18
33	BRONPASS	Hanlim Pharm. Co., Ltd.	Prepared Rehmannia Root·Moutan Root Bark·Schisandra Fruit·Asparagus Tuber·Scutellaria Root·Apricot Kernel·Stemonae Radix soft ext.(1.4～1.7→1)·Corn starch mixed dried products (4.8:1)	Acute bronchitis treatment	2021.4.9
34	FEXUCLUE Tablet	Daewoong Pharmaceuticals	Fexuprazan HCl	Esophageal reflux disease treatment	2021.12.30
35	SkyCovione Multi Injection	SK bioscience Co., Ltd.	SARS-CoV-2 spike protein RBD antigen (genetic recombination)	Prevention of COVID-19	2022.6.29.
36	Envlo Tablets 0.3 mg	Daewoong Pharmaceuticals	Enavogliflozin	Antidiabetics	2022.11.30

※ Excluding revoked items

1.3. Approval of Orphan Drugs

A total of 37 items of orphan drugs were approved in 2023 (including 2 new orphan drugs), in which 3 manufactured and 34 imported items, and 22 chemical drugs, 14 biologics and 1 advanced biological products were approved. Additionally, 26 ingredients were approved, which is composed of 13 ingredients of chemical drugs and 12 ingredients of biologics (refer to Table 20).

Table 20. Orphan Drugs Approved in 2023

(Unit: Number of items)

Category	Total (number of ingredients)	Chemical Drugs	Biologics	Advanced Biological Products	Herbal Medicinal Products
Manufac-turered	3 (2)	3 (2)	0 (0)	0 (0)	0 (0)
Imported	32 (22)	19 (11)	12 (10)	1 (1)	0 (0)
New Orphan Drugs	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)
Total	37 (26)	22 (13)	14 (12)	1 (1)	0 (0)

The orphan drugs approved since 2014 shows that the number of approved items each year maintained similar until 2014, but in 2015, approved items number escalated, reaching 49 items.

After 2016, orphan drug approval was on decline with 34 items in 2016, 18 items in 2017, 17 items in 2018, 11 items in 2019, 28 items in 2020, 22 items in 2021, 29 items in 2022 and 37 items in 2023 which was the largest number after 2015 (refer to Table 21, Figure 4).

Table 21. Number of Orphan Drugs Approved Annually (2012~2023)

(Including revoked and withdrawn items)

(Unit: Number of items)

Category	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Approval	27	28	28	49	34	18	17	11	28	22	29	**37**

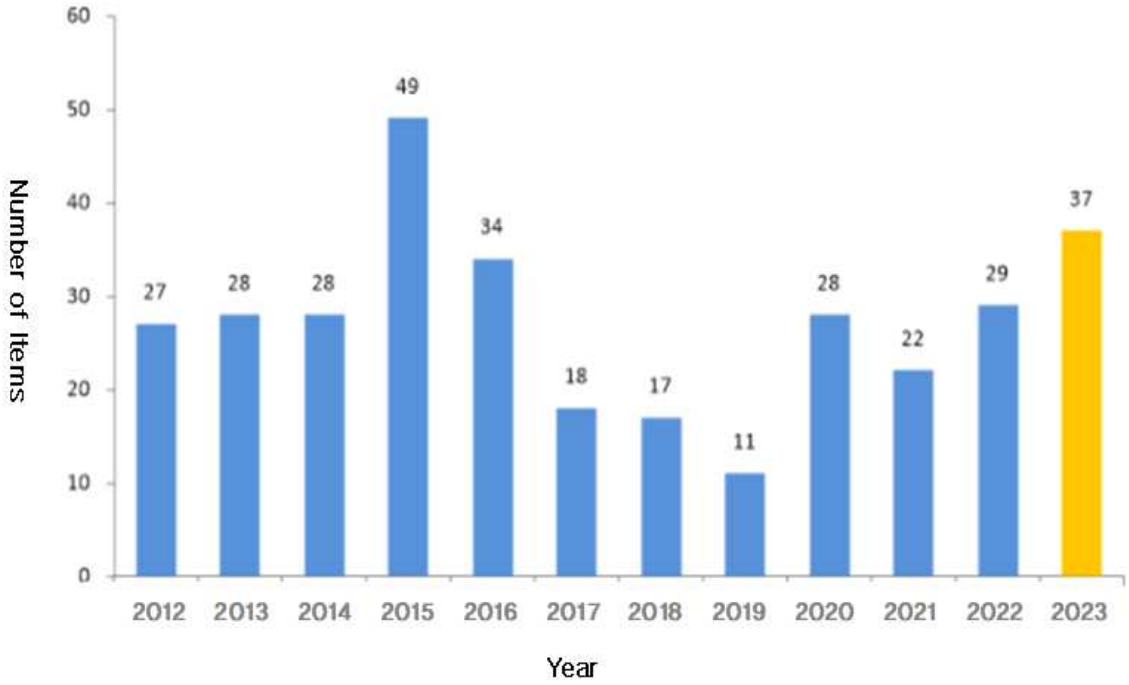

Figure 4. Number of Orphan Drugs Approved (2012~2023)

In addition, a total of 22 ingredients were newly designated as orphan drugs in 2023 (refer to Table 22).

Table 22. Ingredients of Newly Designated Orphan Drugs in 2023

No.	Ingredient (generic name)	Indication
1	Chlormethine hydrochloride (gel)	Localized treatment of early stage mycosis fungoides cutaneous T-cell lymphoma (MF-type CTCL) who have previously received skin-directed therapy
2	Ocrelizumab (injection)	Multiple sclerosis
3	Epcoritamab (injection)	Relapsed or refractory diffuse large B-cell lymphoma after two or more systemic therapies
4	Rosanolixizumab (injection)	Treatment of systemic myasthenia gravis in patients who are positive for anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibodies and who require add-on therapy with corticosteroids or non-steroidal immunosuppressive agents
5	Fidanacogene elaparvovec (injection)	Hemophilia B in patients aged 18 and older
6	Pirtobrutinib (tablets)	Monotherapy in adult patients with relapsed or refractory mantle cell lymphoma who have been previously treated with BTK inhibitors
7	Vorsoritide (injection)	Achondroplasia without closed osteopiphysis
8	Danicopan (tablets)	Add-on to Rabulizumab or Eculizumab in the treatment of adult patients with paroxysmal nocturnal hemoglobinuria with symptoms or signs of extravasation hemolysis
9	Treprostinil sodium (inhalation)	Pulmonary hypertension due to interstitial lung disease
10	Lutetium bipivotide tetraxetan (injection)	Treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (MCRPC) who have previously received androgen receptor pathway inhibition (ARPI) therapy and taxane-based chemotherapy.
11	Thienopyrimidines as Selective phosphodiesterase 4B inhibitors (tablets)	Treatment of idiopathic pulmonary fibrosis
12	Dinutuximab beta (injection)	Treatment of patients with high-risk neuroblastoma who have received myeloablative therapy and stem cell transplantation after having previously received induction chemotherapy and achieved a partial response or better, and patients who have a history of relapsed or refractory neuroblastoma, with or without remaining disease, for 12 months or more
13	Fecal microbiome (liquid)	Prevention of recurrent clostridium difficile infection in adults aged 18 and older
14	Active Eptacog Alfa (injection)	Severe postpartum hemorrhage with insufficient hemostasis with uterine contractions

No.	Ingredient (generic name)	Indication
15	Odevixibat (capsule)	Treatment of progressive familial intrahepatic cholestasis in patients 6 months of age and older
16	Etranacogene dezaparvovec (injection)	Treatment of severe and moderate hemophilia B without factor 9 inhibitor in adults (congenital factor 9 deficiency)
17	Momelotinib (tablets)	Intermediate- or high-risk myelofibrosis in adults with anemia (primary myelofibrosis, myelofibrosis after polycythemia vera, or myelofibrosis after essential thrombocythemia)
18	Disintegrin and metalloproteinase with recombinant thrombospondin motif 13 (injection)	Congenital thrombotic thrombocytopenic purpura due to ADAMTS13 deficiency
19	Vutrisiran sodium (injection)	Hereditary transthyretin amyloidosis (hATTR amyloidosis)
20	Bemarituzumab (injection)	Patients with locally advanced unresectable or metastatic gastric and gastroesophageal junction cancer that overexpresses FGFR2b and is negative for human epidermal growth factor receptor 2 (HER2)
21	Tarlatamab (injection)	Treatment of adult patients with advanced Non-small cell lung cancer whose disease has progressed despite 2 or more prior therapies.
22	Sotatercept (injection)	Treatment of Pulmonary Arterial Hypertension

1.4. Approval and Notification Status by Major Therapeutic Class

In the descending order, the ratio of drug products approved and notified in 2023 by therapeutic class are as follows: metabolic drugs such as antidiabetic agents, etc. (35.6%), nervous system drugs such as antipyretics, analgesics and anti-inflammatory drugs, etc. (14.0%), circulatory system drugs such as anti-hypertensive drugs, etc. (13.4%), digestive system drugs such as stomach ulcer drugs, etc. (5.8%) and anti-allergic drugs such as antihistamines, etc. (3.9%) (refer to Table 23 and Figure 5).

Table 23. Number of Approved and Notified Items by Therapeutic Class in 2023

(including revoked and withdrawn items)

(Unit: Number of items)

Classification / Total	Nervous System	Circulatory System	Digestive System	Metabolism		Sensory Organ Drugs	Tumor Drugs	Dermtologic Drugs	Antiallergic	Others
				Others	Antidiabetics					
1,300	182 (14.0%)	174 (13.4%)	75 (5.8%)	36 (2.8%)	426 (32.8%)	45 (3.5%)	36 (2.8%)	25 (1.9%)	51 (3.9%)	250 (19.2%)
				462 (35.5%)						

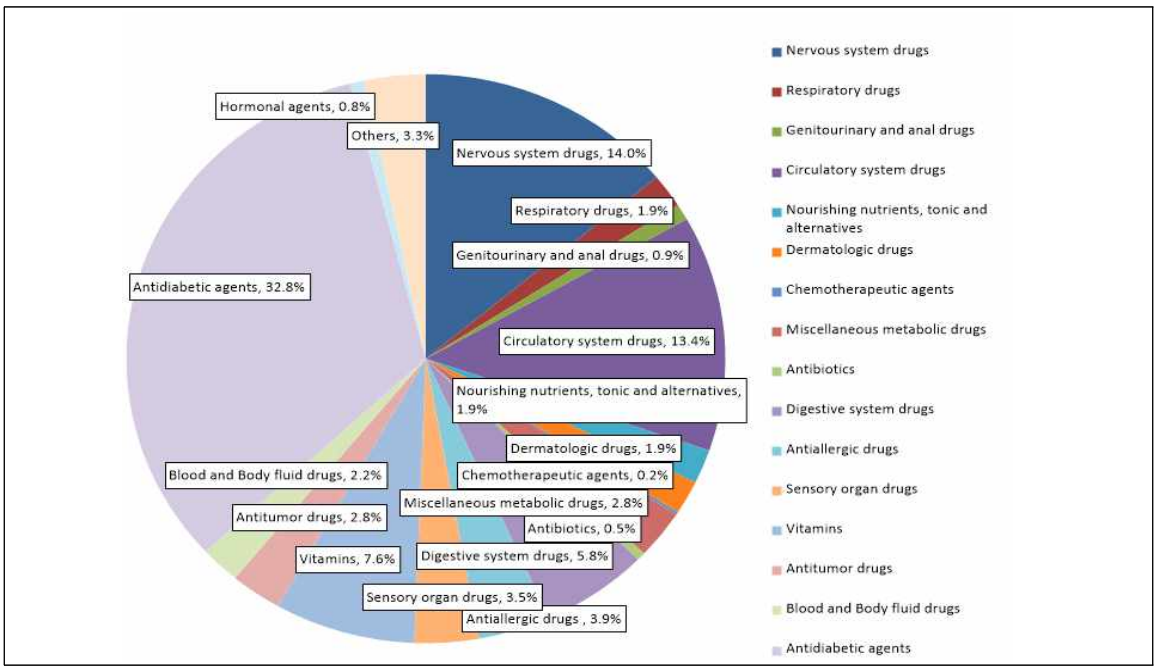

Figure 5. Distribution Status of Approved and Notified Drugs by Major Therapeutic Class in 2023

Given that the approval and notification status each year by therapeutic class, metabolic drugs (including anti-diabetics), nervous system drugs, circulatory system drugs, vitamins, digestive system drugs and anti-cancer drugs accounted for the majority. The approved/ notified drugs that accounted for the largest portion in 2023 were anti-diabetic drugs(33%), which decreased by 8% from 2022 (Figure 6).

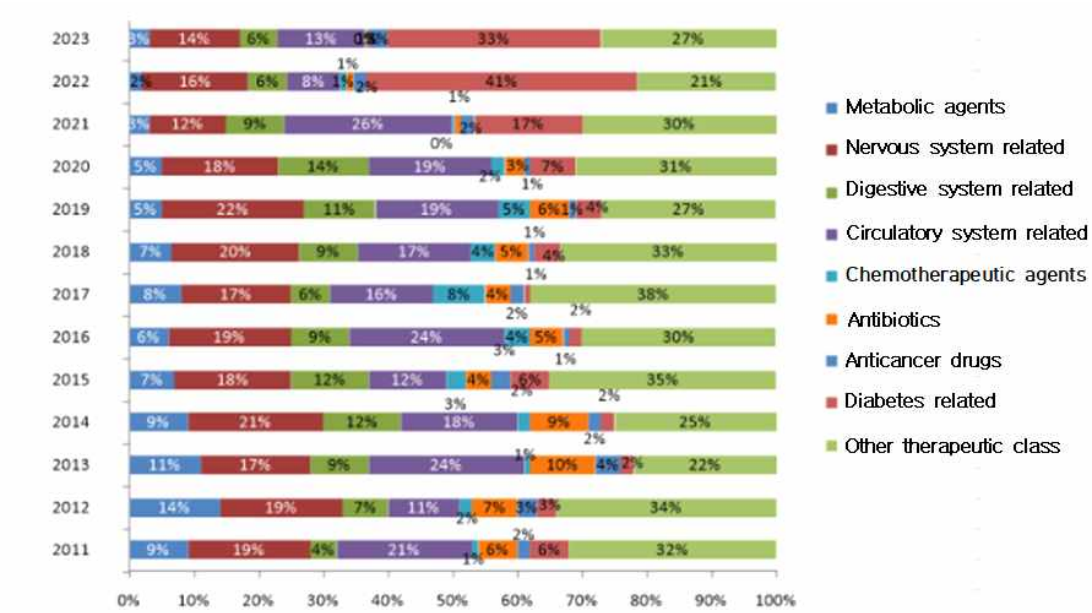

Figure 6. Ratio of Approved and Notified Drugs by Drug Therapeutic Class by Year (2011～2023)

Further analyzing by efficacy, it is shown that 426 items (32.8%) of anti-diabetics were approved, thereby occupying the most of approved items in 2023 and have been within the top 5 category since 2020. Then 120 items (9.2%) of antipyretics, analgesics, and anti-inflammatory drugs, 87 items (6.7%) of miscellaneous vitamin preparations, 77 items (5.9%) of antihypertensive and 57 items (4.4%) of miscellaneous circulatory system drugs followed in order (refer to Table 24).

Table 24. Detailed Classification of Top 5 Approved Items (2019~2023)

(Including revoked and withdrawn items)

No.	2019		2020		2021		2022		2023	
	Detailed Classification	Number of items	Detailed Classification	Number of items	Detailed Classification	Number of items	Detailed Classification	Number of items	Detailed Classification	Number of items
1	Antihypertensive	482 (10.0%)	Miscellaneous circulatory system drug	240 (7.7%)	Antiarteriosclerotic agents	377 (18.9%)	Antidiabetics	599 (41.3%)	Antidiabetics	426 (32.8%)
2	Miscellaneous central nervous system drug	374 (7.8%)	Peptic ulcer drugs	227 (7.3%)	Antidiabetics	335 (16.8%)	Antipyretics, analgesics, and anti-inflammatory drugs	120 (8.3%)	Antipyretics, analgesics, and anti-inflammatory drugs	120 (9.2%)
3	Antipyretics, analgesics, and anti-inflammatory drugs	351 (7.3%)	Antidiabetics	221 (7.1%)	Anticoagulants	160 (8.0%)	Miscellaneous vitamin preparation	67 (4.6%)	Miscellaneous vitamin preparation	87 (6.7%)
4	Peptic ulcer drugs	340 (7.1%)	Antipyretics, analgesics, and anti-inflammatory drugs	190 (6.1%)	Miscellaneous circulatory system drug	123 (6.2%)	Miscellaneous circulatory system drugs	61 (4.2%)	Antihypertensive	77 (5.9%)
5	Antiarteriosclerotic agents	261 (5.4%)	Antiarteriosclerotic agents	175 (6.0%)	Antipyretics, analgesics, and anti-inflammatory drugs	108 (5.4%)	Autonomic nervous system drugs	43 (3.0%)	Miscellaneous circulatory system drugs	57 (4.4.%)
	Number of drug products approved and notified in 2019	4,809 (100%)	Number of drug products approved and notified in 2020	3,110 (100%)	Number of drug products approved and notified in 2021	1,992 (100%)	Number of drug products approved and notified in 2022	1,451 (100%)	Number of drug products approved and notified in 2023	1,300 (100%)

Table 25. Drug Products Approved and Notified in 2023 by Major Therapeutic Class

Classification	Detailed Classification	Number of items
Nervous System Drugs	General anesthetics	2
	Hypnotic sedatives	10
	Antiepileptics	5
	Antipyretics, analgesics, and anti-inflammatory drugs	120
	Stimulants, excitants	0
	Antivertigo drugs	0
	Psychotropics	28
	Miscellaneous central nervous system drugs	11
	Local anesthetics	0
	Skeletal muscle relaxants	1
	Autonomic nervous system drugs	1
	Antispasmodics	2
	Diaphoretics, anhidrotics	2
	Subtotal	182
Ophthalmology and ENT	Ophthalmic preparations	34
	Otic and nasal agents	11
	Subtotal	45
Circulatory System Drugs, and Blood and Body Fluid Drugs	Antiarrhythmic drugs	0
	Antihypertensives	77
	Capillary stabilizers	6
	Vasodilators	3
	Antiarteriosclerotic agents	31
	Miscellaneous circulatory system drugs	57
	Blood substitutes	0
	Hemostatics	0
	Anticoagulants	22
	Miscellaneous blood and body fluid drugs	6
	Subtotal	202
Respiratory and Antiallergic Drugs	Antihistamines	18
	Certified therapeutic agents (including non-specific immunosuppressant)	12
	Miscellaneous antiallergic drugs	21
	Antitussive expectorants	16
	Inhalation treatment preparations	7
	Miscellaneous respiratory drugs	2
	Tuberculostatics	0
	Subtotal	76

Classification	Detailed Classification	Number of items
Digestive System Drugs	Dental and oral drugs	2
	Peptic ulcer drugs	23
	Stomachics and digestives	8
	Antacids	2
	Emetics and antiemetics	7
	Cholagogues	0
	Probiotics	12
	Purgatives and clysters	15
	Miscellaneous digestive system drugs	6
	Subtotal	75
Urinary and Reproductive System Drugs	Urinary tract antiseptics	1
	Contraceptives	3
	Genito-urinary agents (including venereal disease preventives)	3
	Hemorrhoidal preparations	2
	Miscellaneous urogenital and anal organ drugs	3
	Subtotal	12
Metabolic Drugs	Vitamin A and D preparations	3
	Vitamin B1 preparations	0
	Vitamin B preparations (excluding vitamin B1)	1
	Vitamin C and P preparations	0
	Vitamin E and K preparations	0
	Multivitamin preparations (excluding multivitamin complex with A and D)	5
	Miscellaneous vitamin preparations	87
	Calcium preparations	2
	Nourishing nutrients, tonic and alternatives	2
	Mineral preparations	2
	Protein and amino acid preparations	10
	Miscellaneous nourishing nutrients, tonic and alternatives	9
	Liver disease drugs	10
	Antidotes	4
	Gout preparations	0
	Enzyme preparations	4
	Comprehensive metabolic preparations	0
	Low-content vitamin and mineral preparations	3
	Miscellaneous metabolic drugs	18
	Subtotal	160
Antidiabetic Drugs	Antidiabetics	426
	Subtotal	426

2

Approval Status of Drugs (Chemical Drugs)

2. Approval Status of Drugs (Chemical Drugs)

Regarding the chemical drugs approved in 2023 by the review type, it is found that 29 new drugs, 22 orphan drugs, 390 drugs requiring data submission (including 15 incrementally modified drugs), and 2 drug substances were approved. Among the drugs requiriwng data submission (375 items), those with new salts or isomers had the highest ratio by 50.4% (189 items). They were followed by new composition drugs at 24.5% (92 items) and new dosage form (same route of administration) at 13.3% (50 items)(refer to Table 26).

Table 26. Drugs Approved in 2023 by Review Type (Chemical drugs)

<table>
<tr><th>Type</th><th colspan="2">Review Type</th><th colspan="2">Number of Approved Items</th></tr>
<tr><td>1</td><td rowspan="2">New drugs</td><td>New drugs</td><td rowspan="2">29</td><td>29</td></tr>
<tr><td>2</td><td>New orphan drugs</td><td>0</td></tr>
<tr><td>3</td><td colspan="2">Orphan drugs</td><td colspan="2">22</td></tr>
<tr><td>4</td><td colspan="2">Drugs requiring data submission</td><td colspan="2">390</td></tr>
<tr><td rowspan="2">4-1</td><td rowspan="2">Incrementally modified drugs</td><td>New composition</td><td rowspan="2">15</td><td>14</td></tr>
<tr><td>New drug therapeutic class</td><td>1</td></tr>
<tr><td>4-2</td><td rowspan="9">Drugs requiring data submission</td><td rowspan="2">Drugs containing new salts, isomers, low molecular weight synthetic peptides,etc. as active ingredients</td><td rowspan="9">375
(100%)</td><td rowspan="2">189(50.4%)</td></tr>
<tr><td>4-3</td></tr>
<tr><td>4-4</td><td>New therapeutic class</td><td>1(0.3%)</td></tr>
<tr><td>4-5</td><td>New composition</td><td>92(24.5%)</td></tr>
<tr><td rowspan="2">4-6</td><td>Change in strength</td><td>41(11.0%)</td></tr>
<tr><td>New route of administration</td><td>0(0.0%)</td></tr>
<tr><td rowspan="2">4-7</td><td>New mode of administration/dosage</td><td>2(0.5%)</td></tr>
<tr><td>Enzymes, yeasts and microbial agents of novel origin (pharmacologically nearly equivalent)</td><td>0(0.0%)</td></tr>
<tr><td>4-8</td><td rowspan="2">New dosage form (same route of administration)</td><td rowspan="2">50(13.3%)</td></tr>
<tr><td>4-9</td></tr>
<tr><td>5</td><td colspan="2">Drug substances</td><td colspan="2">2</td></tr>
</table>

In 2023, the drug approval system underwent the following changes.

To prepare for medical crisis such as unexpected natural disasters and infectious diseases, the measures has been established to accept multiple standards for active ingredient in-house specification of all substances which were started for cold medicines. In June 2023, the subjects for the “official communication channel for medical products” pilot operation were expanded to all drugs requiring data submission, so that the results of consultation during approval and review process can be incorporated into the review comments for approval. In addition, “System for Preliminary Notice on the Date of Applying Post-Approval Changes” was introduced to make it possible to change the effective date of post-approval changes as requested by a company to facilitate the approval management. In order to prevent confusion and reduce trial and error for the smooth settlement of the system, the pilot program will be conducted first for new and orphan drugs, and then expanded to other drugs.

2.1. Approval Status of New Drugs

The number of new drugs approved in 2023 was 29 items (5 manufactured items and 24 imported items), increased by 50% compared to 2022. The top efficacy classifications of the approved items were nervous system drugs (7 items), anti-diabetics and anti-tumor agents (6 items respectively), circulatory system drugs and drugs for blood/body fluids, respiratory system drugs and anti-allergic drugs (3 items respectively) (refer to Table 27 to Table 28).

Table 27. Approval Status of Manufactured/ Imported New Drugs (2015-2023) (Chemical Drugs)

(Unit: Number of Items)

	2015	2016	2017	2018	2019	2020	2021	2022	2023
Manufactured	6	2	1	2	4	5	4	5	5
Imported	22	22	20	9	28	29	19	15	24
Total	28[1)]	24[2)]	21[3)]	11[4)]	32[5)]	34[6)]	23[7)]	20[8)]	29[9)]
Year-on-Year Increase (%)	-31.7%	-14.3%	-12.5%	-47.6%	190.9%	6.3%	-32.4%	-13.0%	49.5%

1) Includes 4 new drugs with a post-approval change including revocation from the orphan drug list in 2015:
(Revoked from the orphan drug list) Xtandi Soft Capsule 40 mg, Volibris Tablet 5 mg, 10 mg and Zytiga Tablet 250 mg

2) Includes 4 drugs designated as both new drug and orphan drug, and 3 new drugs with a post-approval change including revocation from the orphan drug list in 2016 :
(New orphan drug) Tecfidera Cap. 120, 240 mg, Ofev Soft Cap. 100, 150 mg
(Revoked from the orphan drug list) Jakavi Tab. 5, 15, 20 mg

3) Includes 4 new drugs with a post-approval change including revocation from the orphan drug list in 2017: (Revoked from the orphan drug list) Pomalyst Cap. 1, 2, 3, 4 mg

4) Includes 3 items which were approved as both new drug and orphan drug in 2018:
(New orphan drug) Prevymis Injection and Prevymis Tab. 240 mg, 480 mg

5) Includes 1 drug designated as both new drug and orphan drug, and 3 new drugs with a post-approval change including revocation from the orphan drug list in 2019:
(New orphan drug) Cerdelga Cap. 84 mg
(Revoked from the orphan drug list) Cabometyx Tab. 20, 40, 60 mg

6) Includes 6 new drugs with a post-approval change including revocation from the orphan drug list in 2020:
(Revoked from the orphan drug list) Venclexta Tab. 10, 50, 100 mg and Alunbrig Tab. 30, 90, 180 mg

7) Includes 2 new drugs with a post-approval change including revocation from the orphan drug list in 2021:
(New orphan drug) Galafold Capsule
(Revoked from the orphan drug list) Calquence Capsule 100 mg

8) Includes 2 new drugs with a post-approval change including revocation from the orphan drug list in 2022:
(Revoked from the orphan drug list) Lorviqua 25, 100 mg tablet (lorlatinib)

9) Includes 1 new drug with post-approval change including revocation from orphan drug list in 2023:
(Revoked from the orphan drug list) Brukinsa capsule 80mg (Zanubrutinib)

Table 28. Approved New Drugs by Detailed Classification (2015-2023) (Chemical Drugs)

(Unit: number of items)

	Nervous system drugs	Circulatory system and blood and body	Respiratory system and antiallergic drugs	Genitourinary system drugs	Diabetics	Miscellaneous metabolic drugs	Chemotherapeutics agents	Antitumor agents	Antibiotics	Sensory organs	Liver disease drugs	Radiological diagnosis	hormonal medications	Dermatologic drugs	Digestive system drugs	Drugs for public hygiene	Total
2015	8	5	1	0	2	0	5	4	2	0	0	1	0	0	0	0	28
2016	2	6	2	0	0	0	2	9	0	0	0	0	3	0	0	0	24
2017	0	3	4	0	0	0	2	9	1	0	1	0	0	1	0	0	21
2018	0	1	0	0	2	0	4	0	0	0	0	1	0	1	2	0	11
2019	7	0	0	0	0	1	4	12	0	3	0	0	0	0	4	1	32
2020	9	3	3	0	0	1	5	13	0	0	0	0	0	0	0	0	34
2021	2	8	3	0	0	0	0	4	0	1	0	1	0	2	2	0	23
2022	2	5	2	1	1	0	4	3	1	0	0	0	0	0	1	0	20
2023	7	3	3	0	6	2	1	6	0	1	0	0	0	0	0	0	29

The product names, manufacturers, dates of approval, active ingredients, efficacy and effectiveness, mechanism of action for new drugs approved in 2023 in the order of approval dates are as follows:

“Brukinsa capsule 80mg (Zanubrutinib)” (BeiGene Korea, approved on February 24, 2022, post-approval changes-new drug designation approved on July 10, 2023) is indicated for the monotherapy of adult patients with mantle cell lymphoma (MCL) or Waldenström’s macroglobulinemia (WM) who have received one or more prior therapies. The active ingredient, **zanubrutinib**, is a selective inhibitor of Bruton's kinase (BTK, a kinase involved in cell adhesion and survival in certain B-cell malignancies) and acts by forming a covalent bond with Cys481 in the BTK ATP pocket to irreversibly inhibit BTK activity.

Three items including **“Bosulif Tablet 100mg (Bosutinib monohydrate)”** (Pfizer Pharmaceuticals Korea Limited, approved on January 12, 2023) are indicated for the treatment of newly diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) and chronic phase, accelerated phase (AP), or blast phase (BP) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) that is resistant or intolerant to prior therapy. The active ingredient of the drug is **bosutinib monohydrate**, which inhibits BCR-ABL kinase, a protein that is activated on the Philadelphia chromosome and acts as a cell signaling substance to promote abnormal cell growth and division.

“Zeposia Capsule 0.92mg (Ozanimod Hydrochloride)” and **“Zeposia Capsule Starter Pack 0.23mg/0.46mg (Ozanimod Hydrochloride)”** (BMS Pharmaceutical Korea Ltd, approved february 23, 2023) are indicated for the treatment of moderate to severe active ulcerative colitis in

adult patients who have inadequate response to, lost response to, or are intolerant to conventional therapies (5-ASA, corticosteroids, immunosuppressants) or biopharmaceuticals. The active pharmaceutical ingredient, **Ozanimod hydrochloride**, exerts its therapeutic effects by modulating immune responses through potent activation of S1P1R (sphingosine-1-phosphate 1 receptor) and S1P5R (S1P 5 receptor) receptors.

"Vadanem Tablet 150 mg (Vadadustat)" and the other item (Mitsubishi Tanabe Pharma Korea Co., Ltd., approved on March 13, 2023) are indicated for the treatment of anemia in patients with chronic kidney disease. The active pharmaceutical ingredient, **Vadadustat**, functions as a small molecule inhibitor of HIF-prolyl 4-hydroxylase (HIF-PHs), thereby stimulating erythropoiesis and enhancing red blood cell production.

Six items, including **"Mounjaro Prefilled Pen Inj. 10mg/0.5mL (Tirzepatide)"** (Lily Korea Ltd., approved on June 28, 2023) used as an adjunct to diet and exercise therapy to improve blood sugar control in patients with type 2 diabetes either as monotherapy or combination therapy. The active pharmaceutical ingredient, **filgotinib maleate**, selectively binds to the GIP (glucose-dependent insulinotropic polypeptide)/GLP-1 (glucagon-like peptide-1) receptors in the pancreas, leading to increased insulin secretion from pancreatic beta cells, attenuation of systemic sensitivity, and reduction in blood glucose levels by suppressing glucagon secretion.

“PAXLOVID Tablets(nirmatrelvir, ritonavir)” (Pfizer Pharmaceuticals Korea Limited, approved on July 14, 2023) is indicated for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults at increased risk of progression to severe coronavirus disease 2019 (COVID-19), including hospitalization or death. **“Nirmatrelvir”** an active ingredient, exerts its antiviral effect by inhibiting 3CL protease (Mpro), an enzyme essential for viral replication, which inhibits the production of proteins required for viral replication and transcription, and inhibits the CYP3A (nirmatrelvir degradation) activity of **“Ritonavir”** to maintain **“Nirmatrelvir”** blood concentration.

“Sotyktu Tablets 6 mg (Deucravacitinib)” (BMS Pharmaceutical Korea Ltd., approved on August 3, 2023) is indicated for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for phototherapy or systemic therapy. **“Deucravacitinib”**, an active ingredient, selectively inhibits the tyrosine kinase 2 (TYK2) enzyme, thereby inhibiting the release of pro-inflammatory cytokine and chemokine.

2 items including **“AQUIPTA 10mg tablets (Atogepant)”** (AbbVie Korea Ltd., approved on November 15, 2023) are used to prevent migraine in adults, and **“Atogepant”**, the active ingredient, is a selective inhibitor of CGRP (calcitonin gene-related peptide), which inhibits the development of migraine.

2 items including **“Orkedia Tablets 1 mg (Evocalcet)”** (Kyowa Kirin Korea Co., Ltd., approved on November 15, 2023) are a treatment for

secondary hyperparathyroidism associated with chronic kidney failure patients undergoing dialysis. The active ingredient, **“Evocalcet”**, is a type 2 calcium analog agonist (Calcimimeitcs), which inhibits the secretion of PTH (parathyroid hormone) by acting on calcium receptors on the surface of parathyroid cells.

5 items including **“LATUDA 20mg tablets (Lurasidone hydrochloride)”** (BUKWANG PHARM. CO., LTD., approved on November 23, 2023) are indicated for the treatment of schizophrenia in adolescents 13 years of age and older and adults and major depressive episodes associated with type 1 bipolar disorder in children 10 years of age and older and adults. The active ingredient, **“Lurasidone hydrochloride”**, is estimated to exert its effects by antagonizing dopamine D2 receptors and serotonin 5-HT2A and 5-HT7 receptors.

“Pivlaz injection (Clazosentan disodium)” (Idorsia Pharmaceuticals Korea Co., Ltd., approved on December 7, 2023) is indicated for the prevention of cerebral vasospasm and cerebral infarction and cerebral ischemic symptoms associated with cerebral vasospasm after treatment of aneurysmal subarachnoid hemorrhage. **“Clazosentan disodium”**, the active ingredient, is a selective inhibitor of endothelin type A (ETA) receptors, which inhibits cerebral vasospasm.

“TUKYSA film-coated tablet 50 mg (Tucatinib hemiethanolate)” (MSD KOREA Co., Ltd., approved on December 14, 2023) is indicated in combination with trastuzumab and capecitabine for the treatment of adult patients with HER2-positive, locally advanced or metastatic

breast cancer who have received at least two prior anti-HER2 therapies. The active ingredient, **“Tucatinib”**, inhibits the phosphorylation of HER2 and HER3, thereby inhibiting cell signaling downstream and cell proliferation and inducing HER2-induced tumor cells apoptosis.

Table 29. New Drugs Approved in 2023 (Chemical Drugs)

No.	Manufacturered/ Imported	Product Name	Company	Date of Approval (Designation)	Main ingredient	Efficacy/Effectiveness (partially omitted)
1	Imported	Brukinsa capsules 80mg (Zanubrutinib)	BeiGene Korea	Initial Approval Date 2022-02-24 (Revoked from orphan drug list, switched as new drug on 2023-07-10)	Zanubrutinib	**Mantle Cell Lymphoma(MCL)** Monotherapy in adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy **Waldenstrom Macroglobulin -emia(WM)** Monotherapy in adult patients with Waldenström macroglobulin -emia(WM) who have received at least one prior therapy **Marginal Zone Lymphoma (MZL)** Monotherapy in adult patients with relapsed/refractory marginal zone lymphoma (MZL) who have received at least one prior therapy **Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)** Monotherapy in treatment-naive adult patients with chronic lymphocytic leukemia(CLL) or small lymphocytic lymphoma (SLL) who are either 65 years or older, or under 65 years with comorbidities Monotherapy in adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma(SLL) who have received at least one prior therapy.

No.	Manufacturered/ Imported	Product Name	Company	Date of Approval (Designation)	Main ingredient	Efficacy/Effectiveness (partially omitted)
2	Imported	Bosulif Tablet 100mg (Bosutinib Monohydrate)	Pfizer Pharma-ceuticals Korea Limited	2023-01-12	Bosutinib Monohydrate	This drug is used for the treatment of the following adult patients: 1. Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML). 2.. Philadelphia chromosome - positive chronic myeloid leukemia(Ph+ CML) in chronic phase(CP), accelerated phase (AP), or blast phase (BP) who are resistant or intolerant to prior therapy
3	Imported	Bosulif Tablet 400mg (Bosutinib Monohydrate)				
4	Imported	Bosulif Tablet 500mg (Bosutinib Monohydrate)				
5	Imported	RHOPRESSA ophthalmic solution 0.02% (Netarsudil Mesylate)	Santen Pharma-ceutical Korea Co., Ltd.	2023-02-03	Netarsudil Mesylate	Lowering of intraocular pressure for following diseases Open angle glaucoma, ocular hypertension
6	Imported	Zeposia Capsule 0.92mg (Ozanimod Hydrochloride)	BMS Pharma-ceutical Korea Ltd.	2023-02-23	Ozanimod Hydrochloride	Treatment of moderate to severe active ulcerative colitis in adults who have not responded adequately to, lost response to, or are intolerant of conventional therapies (such as corticosteroids and immunosuppressive agents) or biologics
7	Imported	Zeposia Starter Pack 0.23mg/0.46mg (Ozanimod Hydrochloride)				
8	Imported	Vadanem tablets 150mg (Vadadustat)	Mitsubishi Tanabe Pharma Korea Co., Ltd.	2023-03-13	Vadadustat	Treatment of anemia in adult patients with chronic kidney disease on hemodialysis
9	Imported	Vadanem tablets 300mg (Vadadustat)				

No.	Manufacturered/ Imported	Product Name	Company	Date of Approval (Designation)	Main ingredient	Efficacy/Effectiveness (partially omitted)
10	Imported	Mounjaro Prefilled Pen Inj. 2.5mg/0.5mL (Tirzepatide)	Lilly Korea Ltd.	2023-06-28	Tirzepatide	This is administered as an adjunct to diet and exercise therapy to improve glycemic control in adults with type 2 diabetes. - Monotherapy - Combination Therapy
11	Imported	Mounjaro Prefilled Pen Inj. 5mg/0.5mL (Tirzepatide)				
12	Imported	Mounjaro Prefilled Pen Inj. 7mg/0.5mL (Tirzepatide)				
13	Imported	Mounjaro Prefilled Pen Inj. 10mg/0.5mL (Tirzepatide)				
14	Imported	Mounjaro Prefilled Pen Inj. 12.5mg/0.5mL (Tirzepatide)				
15	Imported	Mounjaro Prefilled Pen Inj. 15mg/0.5mL (Tirzepatide)				
16	Imported	PAXLOVID Tablets(nirmatrelvir/ritonavir)	Pfizer Pharma-ceuticals Korea Limited	2023-07-14	Ritonavir, Nirmatrelvir	Mild and moderate Coronavirus Disease 19 (COVID-19) in adults with higher risk of progression to severe COVID-19 including hospitalization or death <Limitation of use> This drug is not approved for pre- or post-exposure prophylaxis of COVID-19
17	Imported	Sotyktu Tablets 6 mg (Deucravacitinib)	BMS Pharma-ceutical Korea Ltd.	2023-08-03	Deucravacitinib	Treatment of moderate-to-severe plaque psoriasis in adult patients with phototherapy or systemic therapy
18	Imported	AQUIPTA 10mg tablets (Atogepant)	AbbVie Korea Ltd.	2023-11-15	Atogepant Monohydrate	Prevention of migraines in adults
19	Imported	AQUIPTA 60mg tablets (Atogepant)				

No.	Manufacturered/ Imported	Product Name	Company	Date of Approval (Designation)	Main ingredient	Efficacy/Effectiveness (partially omitted)
20	Imported	Orkedia Tablets 1 mg (Evocalcet)	Kyowa Kirin Korea Co., Ltd	2023-11-15	Evocalcet	Treatment of secondary hyper-parathyroidism associated with chronic kidney failure patients on dialysis
21	Imported	Orkedia Tablets 2 mg (Evocalcet)				
22	Manufactured	LATUDA 120mg tablets (Lurasidone Hydrochloride)	BUKWANG PHARM. CO., LTD.	2023-11-23	Lurasidone Hydrochloride	1. Schizophrenia in adolescents and adults 13 years of age and older 2. Major depressive episode associated with bipolar disorder type 1 in pediatric patients who are the age of 10 and older and adult patients.
23	Manufactured	LATUDA 20mg tablets (Lurasidone Hydrochloride)				
24	Manufactured	LATUDA 40mg tablets (Lurasidone Hydrochloride)				
25	Manufactured	LATUDA 60mg tablets (Lurasidone Hydrochloride)				
26	Manufactured	LATUDA 80mg tablets (Lurasidone Hydrochloride)				

No.	Manufacturered/ Imported	Product Name	Company	Date of Approval (Designation)	Main ingredient	Efficacy/Effectiveness (partially omitted)
27	Imported	Pivlaz injection (Clazosentan disodium)	Idorsia Pharmaceuticals Korea Co., Ltd.	2023-12-07	Clazosentan disodium	Prevention of cerebral infarction, cerebral ischemic symptoms associated with cerebral vasospasm, and cerebral vasospasm after treatment of aneurysmal subarachnoid hemorrhage Administer this drug to patients with ruptured cerebral aneurysms that have been adequately hemostasized by surgical or endovascular treatment. The decision to administer this medication should be based on the patient's condition, including the severity of the subarachnoid haemorrhage, the amount of clot, and the extent of the cerebral infarction. - Concomitant administration of vasodilators such as nimodipine preparations - WFNS (World Federation of Neurosurgical Surgeon) class V patients - Patients with extensive cerebral infarction - Patients with Fisher classification other than 3* * Localized thrombus or presence of blood >1 mm thick in a layer perpendicular to the CT section (with or without intracerebral or intraventricular hematoma)
28	Imported	TUKYSA film-coated tablet 50 mg (Tucatinib hemiethanolate)	MSD KOREA Co., Ltd.	2023-12-14	Tucatinib hemiethanolate	Combination therapy with trastuzumab and capecitabine for the treatment of adult patients with HER2-positive, unresectable, locally advanced or metastatic breast cancer who have been previously treated with at least 2 anti-HER2 therapies
29	Imported	TUKYSA film-coated tablet 150 mg (Tucatinib hemiethanolate)				

2.2. Approval Status of Orphan Drugs

The chemical drugs approved as orphan drugs in 2023 were 22 items (3 manufactured items, 19 imported items) (refer to Table 30).

Analyzing the approved orphan drugs by their therapeutic class, 10 anti-tumor agents, 4 miscellaneous circulatory system drugs, 3 miscellaneous blood and body fluid drugs, 2 anti-hypertensives, 1 liver disease drug, 1 miscellaneous diagnostic drug and 1 certified therapeutic agents were approved. Out of 14 ingredients of orphan drugs approved in 2023, 2 ingredients (14.3%) were manufactured and 12 ingredients (85.7%) were imported, suggesting that imported orphan drugs (19 items) six times more than domestically manufactured orphan drugs (3 items). It also includes one ingredient newly designated as orphan drug in 2023, four ingredients designated in 2022, two ingredients designated in 2009 and 2021 respectively, and five ingredients designated between 2007 and 2017.

Table 30. Orphan Drugs Approved in 2023 (Chemical Drugs)

No.	Manufactured/Imported	Product Name	Company	Approval Date	Detailed Classification	Efficacy/Effectiveness	Designation Status of Orphan Drugs	
1	Imported	THIOSPAL-P Infusion 15mg, 100mg (Thiotepa)	DONGINPHARMACEUTICAL Co.,Ltd	2023-02-24	Anti-tumor agents	In combination with other chemotherapy regimens for the following conditions: - Conditioning chemotherapy prior to allogeneic or autologous hematopoietic stem cell transplantation (HPCT) in hematologic disorders in adult and pediatric patients, with or without concomitant total body irradiation (conditioning treatment) - When high-dose chemo therapy in combination with hematopoietic stem cell transplantation is appropriate for the treatment of solid	No	338(Designated in 2023)
							Ingre-dient	Thiotepa
							Indica-tion	In combination with other chemotherapy regimens for the following conditions: - Conditioning chemotherapy prior to allogeneic or autologous hematopoietic stem cell transplantation (HPCT) in hematologic disorders in adult and pediatric patients, with or without concomitant total body irradiation (conditioning treatment) - When high-dose chemo therapy in combination

						tumors in adult and pediatric patients		with hematopoietic stem cell transplantation is appropriate for the treatment of solid tumors in adult and pediatric patients
2	Imported	Livmarli Solution (Maralixibat Chloride)	GC Biopharma Corp.	2023-02-28	Liver disease drugs	Treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) >3 months old	No	310 (Designated in 2021)
							Ingre-dient	Maralixibat Chloride
							Indica-tion	Cholestatic ichthyosis in patients with Alagille syndrome
3	Manufac tured	Pharmbio Korea Eltrombopag Olamine Tablets 25mg	Pharmbio Korea Inc.	2023-03-10	Miscellane-ous blood and body fluid drugs	1. Treatment of hypothrombo cytosis in patients with chronic immune (idiopathic) thrombocyto penia who have not had an adequate response to corticosteroids or immuno globulins or splenectomy. This medicine is used only in patients with clinical conditions of hypoplatelet emia that increase the risk of bleeding. It is not intended to normalize platelet counts 2. Treatment of hypothrombo cytosis(platelet count <75×109/L at initiation) for initiation and maintenance of interferon-based therapy in patients with chronic hepatitis C This medicine is used only in patients with hypoplatelet emia, a clinical condition that increases the risk of bleeding, or in patients with chronic hepatitis C who are unable to start interferon-based therapy or have difficulty maintaining interferon-based therapy because of hypoplateletemia. It is not intended to normalize platelet counts 3. In combination with immuno suppressive therapy, for the first-line treatment of pediatric 2 years of age and older and adult patients with severe aplastic anemia or for the treatment of severe aplastic anemia that has not responded adequately to immunosuppressive therapy	No	113 (Designated in 2009)
							Ingre-dient	Eltrombopag
							Indica-tion	Treatment of hypothrombo cytosis in patients with chronic immune (idiopathic) thrombocytopenic purpura who have not responded adequately to corticosteroids, immunoglobulins, or splenectomy
4	Manufac tured	Pharmbio Korea Eltrombopag Olamine Tablets 50mg						
5	Imported	Pemazyre (Pemigatinib) Tablet 4.5mg	Handok Inc.	2023-04-25	Anti-tumo r agents	Locally advanced or metastatic cholangiocarcinoma with fibroblast growth factor receptor 2 (FGFR2) fusions or rearrangements in adults	No	307 (Designated in 2021)
							Ingre-dient	Pemigatinib
							Indica-	Locally advanced or

6	Imported	Pemazyre (Pemigatinib) Tablet 9mg				who have received at least 1 prior systemic therapy	tion	metastatic cholangiocarcinoma in adults with fusion or rearrangement of fibroblast growth factor receptor 2 (FGFR2) who have received at least one prior systemic therapy
7	Imported	Pemazyre (Pemigatinib) Tablet 13.5mg						
8	Imported	Camzyos (mavacamten) capsule 2.5mg	BMS Pharmaceutical Korea Ltd.	2023-05-23	Miscellaneous circulatory system drugs	Treatment to Improve exercise function and attenuate symptoms in adult patients with symptomatic(NYHA class II-III) obstructive hypertrophic cardiomyopathy	No	319 (Designated in 2022)
							Ingre-dient	Mavacamten
9	Imported	Camzyos (mavacamten) capsule 5mg					Indica-tion	Treatment of symptomatic obstructive hypertrophic cardiomyopathy in adults
10	Imported	Camzyos (mavacamten) capsule 10mg						
11	Imported	Camzyos (mavacamten) capsule 15mg						
12	Imported	Welireg (Belzutifan)	MSD KOREA Co., Ltd.	2023-05-23	Anti-tumor agents	Treatment of renal cell carcinoma, central nervous system hemangioblastoma, and pancreatic neuroendocrine tumors not requiring immediate surgery in adult patients with von Hippel-Lindau (VHL) disease	No	315 (Designated in 2022)
							Ingre-dient	Belzutifan
							Indica-tion	Adults in VHL who do not require immediate surgery but need treatment for von Hippel-Lindau (VHL)-associated renal cell carcinoma, central nervous system hemangioblastoma, and pancreatic neuroendocrine tumors
13	Imported	Atepa injection 15mg (Thiotepa)	Acepharma	2023-05-31	Anti-tumor agents	In combination with other chemotherapy regimens for the following conditions: - conditioning treatment prior to allogeneic or autologous hematopoietic stem cell transplantation (HPCT) in hematologic disorders in adult and pediatric patients, with or without concomitant total body irradiation - When high-dose chemo-therapy in combination with hematopoietic stem cell transplantation is appropriate for the treatment of solid tumors in adult and pediatric patients	No	338 (Designated in 2023)
							Ingre-dient	Thiotepa
14	Imported	Atepa injection 100mg (Thiotepa)					Indica-tion	In combination with other chemotherapy regimens for the following conditions: - conditioning treatment prior to allogeneic or autologous hematopoietic stem cell transplantation (HPCT) in hematologic disorders in adult and pediatric patients, with or without concomitant total body irradiation - When high-dose chemo-therapy in combination with hematopoietic stem cell transplantation is appropriate for the treatment of solid tumors in adult and pediatric patients
15	Imported	TRISENOX	REPURE	2023-06-29	Anti-tumor	For use in patients	No	117 (Designated in 2010)

		(arsenic trioxide) injection 2mg/mL	Healthcare Inc.		agents	diagnosed with AML by chromosomal[t(15;17) translocation] and/or genetic [Pro-Myelo cytic Leukemia/ Retinoic - Acid-Receptor -alpha(PML/RAR-alpha) gene] testing. Response rates in other acute myeloid leukemia (AML) subtypes have not been investigated. 1. Remission induction and consolidation therapy with tretinoin in adult patients with newly diagnosed low-risk (leukocytel count ≤10×109/L) acute promyelocytic leukemia 2. Remission induction and consoli dation therapy in adult patients with refractory or re AML(prior therapy must include tretinoin and clapsechemotherapy) The effectiveness and safety of this drug in relapsed acute promyelocytic leukemia after complete remission have not been established.	Ingre-dient	Arsenic trioxide
							Indica-tion	1. Relapsed or refractory acute promyelocytic leukemia 2. Combination therapy with tretinoin in patients with newly diagnosed low-risk (WBC count ≤ 10,000/mcL) acute promyelocytic leukemia
16	Manufac tured	Samjin Sildenafil citrate Tab. 20mg	SAMJIN PHARM. CO.,LTD	2023-07-07	Antihyper tensives	Improving exercise capacity in patients with pulmonary arterial hypertension (WHO Group Ⅰ) in WHO functional classification Ⅱ or Ⅲ(Efficacy of this drug in patients receiving bosentan has not been evaluated.)	No	89 (Designated in 2007)
							Ingre-dient	Sildenafil citrate
							Indica-tion	This drug is used to treat patients with pulmonary arterial hypertension (WHO Group Ⅰ) to improve exercise capacity.
17	Imported	Macrilen Granule (Macimorelin acetate)	NK MEDITECH	2023-09-07	Miscella-neous diagnostic drugs	Diagnosis of growth hormone deficiency in adults	No	325 (Designated in 2022)
							Ingre-dient	Macimorelin acetate
							Indica-tion	Diagnosis of growth hormone deficiency in adults
18	Imported	Tavneos (Avacopan) 10mg hard capsule	MEDITIP	2023-09-21	Certified therapeutic agent (including non-specific immuno suppresants)	Combination with rituximab or cyclophosphamide for the treatment of adults with active, severe granulomatous polyangiitis(GPA) and micro-scopic polyangiitis (MPA)	No	322 (Designated in 2022)
							Ingre-dient	Avacopan
							Indica-tion	Combination therapy with rituximab or cyclophosphamide for the treatment of adult patients with symptomatic, severe granulomatous poly-angiitis(GPA) and microscopic polyangiitis (MPA)
19	Imported	Akeega tab. 100/500mg	Janssen Korea Ltd.	2023-09-25	Anti-tumor agents	Combination therapy with prednisolone in chemotherapy-naïve adult patients diagnosed with BRCA-mutated meta static castration-resistant prostate cancer	No	141(Designated in 2012)
							Ingre-dient	Abiraterone acetate
							Indica-tion	Metastatic castration-resistant prostate cancer previosly treated with chemotherapy including docetaxel
							No	233 (Designated in 2017)
							Ingre-dient	Niraparib

							Indica-tion	1. Maintenance monotherapy in adult patients with platinum-sensitive recurrent ovarian cancer(including fallopian tube cancer or primary peritoneal cancer) who have responded to platinum-based therapy 2. Received prior chemotherapy three times or more 1) BRCA mutation(regardless of platinum sensitivity) who have received 3 or more prior lines of chemotherapy or 2) platinum-sensitive HRD-positive recurrent ovarian cancer(including fallopian tube cancer or primary peritoneal cancer) as mono-therapy in adult patients 3. Monotherapy for maintenance therapy in adult patients with ovarian cancer (including fallopian tube cancer or primary peritoneal cancer) who have responded(partial or complete response) to first-line platinum-based therapy
20	Imported	Akeega tab. 50/500mg						
21	Imported	Uptravi 600mcg (Selexipag)	Janssen Korea Ltd.	2023-10-20	Antihyper tensives	Long-term treatment of adult patients with pulmonary arterial hypertension (WHO Group I) in WHO functional classfication II-III. Efficacy has been proven in patients with idiopathic pulmonary arterial hypertension, inherited pulmonary arterial hypertension, pulmonary arterial hypertension associated with connective tissue disease, and pulmonary arterial hypertension associated with congenital heart disease	No	194 (Designated in 2015)
							Ingre-dient	Selexipag
							Indica-tion	Treatment of patients with pulmonary arterial hypertension in WHO functional class II-IV(WHO Group I)
22	Imported	Mobilia Inj. (Plerixafor)	JW Pharmaceutical)	2023-11-21	Miscellaneous blood and body fluid drugs	Treatment of adult patients with locally advanced or metastatic urothelial carcinoma with FGFR2 or FGFR3 mutations whose disease progressed during or after treatment with at least one chemo therapeutic agent, including platinum-based chemo thera- peutic agents, or whose disease progressed within 12 months of preoperative neo-adjuvant or postoperative adjuvant therapy, including platinum-based chemotherapeutic agents Efficacy of this drug is based on response rate and duration of response; no therapeutic confirmation trials have demonstrated improvement in survival	No	114 (Designated in 2009)
							Ingre-dient	Plerixafor
							Indica-tion	Enhancement of mobilization of hematopoietic stem cells from peripheral blood for autologous stem cell transplantation and stem cell apheresis in patients with lymphoma and multiple myeloma

* Detailed approval information (efficacy/effectiveness, administration/usage, and precautions for use) is available at http://nedrug.mfds.go.kr.

2.3. Approval Status of Incrementally Modified Drugs

“Incrementally modified drugs” refers to the drugs that the Minister of Food and Drug Safety designates as incrementally modified or medicinally advanced in its safety, efficacy, and effectiveness (medication compliance, convenience, etc.) compared to approved/ notified drugs requiring data submission under Article 2(8) of the “Regulations for Pharmaceutical Approval, Notification and Reviews.“

The development types of recently approved incrementally modified drugs are as follows: From 2016 to 2017, combination drugs with new composition of active substances (drugs containing 2 or more active ingredients in one product) were noticeably developed. In 2018, 6 sustained-release tablet items with improved administration and dosage by reducing the number of intakes were designated as incrementally modified drugs. In 2019, 11 items with improved efficacy and 2 items with improved efficacy were approved, totaling to approval of 13 designated incrementally modified drugs. In 2020, 5 items with improved effectiveness, including 4 sustained-release tablet items with improved intake convenience and compliance by a change in dosage form and route of administration and dosage and 1 item with improved efficacy (6 items in total) were approved as incrementally modified drugs.

In 2021, 3 new combination drugs with new compositions of active ingredients and 4 items with improved effectiveness through change in the route of administration with new dosage forms (7 items in total) were designated as incrementally modified drugs. In 2022, 9 items, including combination drugs with improved compliance through new compositions of active ingredients(7 items) and with improved efficacy through change in the route of administration(2 items) were designated as

incrementally modified drugs. In 2023, 15 items, including 14 new combination drugs with new compositions of active ingredients and 1 item improved for effectiveness with different indications and usage were approved (refer to Table 31).

Table 31. Type of Incrementally Modified Drugs in 2016~2023

Year	New Composition or Compounding Ratio	Distinctly different Efficacy/Effec-tiveness Addition	New Dosage Form (Same Route of Administration)	New Route of Administration	Total
2016	22	0	1	1	24
2017	7	0	4	0	11
2018	0	0	6	0	6
2019	13	0	0	0	13
2020	2	0	4	0	6
2021	3	0	0	4	7
2022	7	0	0	2	9
2023	14	1	0	0	15
Total	68	1	15	7	91

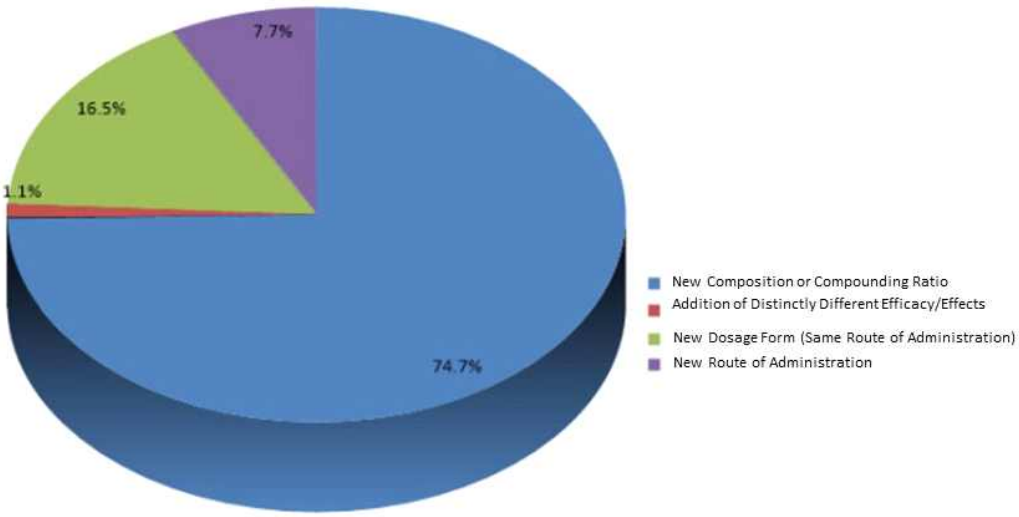

Figure 7. Ratio of Approval by Type of Incrementally Modified Drug (2016~2023)

The Ministry of Food and Drug Safety has been publishing the 「Casebook of approved incrementally modified drugs」 (Guidance for applicants) since November 2011. The 15 items approved as incrementally modified drugs in 2023 include 12 ingredients (refer to Table 32) and will be reflected in the 「Casebook of approved incrementally modified drugs」 (Guidance for applicants) for 2024, including the approval status, product type-specific status, detailed designation criteria by case, non-designated cases, etc.

Table 32. List of Incrementally Modified Drugs (2009~2023)

No.	Product name	Company	Approval date	Detailed classification	Remarks
1	Amosartan Tab. 5/50mg	Hanmi Pharm. Co., Ltd.	2009-03-31	Antihypertensives	Change of active substance type or compounding ratio
2	Amosartan Tab. 5/100mg				
3	COZAAR XQ Tablet 5/50mg	MSD Korea Co., Ltd. → (transfer) Organon Korea Co., Ltd	2009-11-20		
4	COZAAR XQ Tablet 5/100mg				
5	Potastine OD Tab.	Hanmi Pharm . Co., Ltd.	2010-02-11	Antihistamines	Salt and dosage form changes
6	CLANZA CR Tab. (Aceclofenac)	Korea United Pharm. Inc.	2010-04-14	Antipyretics, analgesics, and antiinflammatory drugs	Change in dosage form, strength and mode of administration/dosage
7	Ridrone plus tablet	Pacific Pharmaceuticals	2010-06-23	Miscellaneous metabolic drugs	Change of active substance type or compounding ratio
8	RISENEX-PLUS Tab.	Celltrion Pharm, Inc.	2010-06-23		
9	RISENPLUS TAB	DAEWOONG PHARMACEUTICAL CO.,LTD.	2010-06-23		
10	Amosartan Tab. 10/50mg	Hanmi Pharm. Co., Ltd.	2010-10-15	Antihypertensives	Change of active substance type or compounding ratio
11	COZAAR XQ Tablet 10/50mg	MSD Korea Co., Ltd. → (transfer) Organon Korea Co., Ltd	2010-10-15		
12	Ultracet ER Tab.	Janssen Korea Ltd.	2010-11-22	Antipyretics, analgesics, and antiinflammatory drugs	Change in dosage form, strength and mode of administration/dosage
13	ROXFEN CR Tablet	SHIN POONG PHARM. CO., LTD.	2011-03-18	Antipyretics, analgesics, and antiinflammatory drugs	Change in dosage form, strength and mode of administration/dosage
14	Pletaal SR Capsules	Korea Otsuka Pharmaceutical	2011-04-19	Miscellaneous blood and body fluid drugs	Change in dosage form, strength and mode of administration/dosage
15	Apetrol ES oral suspension	LG Life Science→ (name change) LG Chem Ltd.	2012-03-27	anti-tumor drugs	Change in strength and mode of administration/dosage
16	Ridonel D Tab.	Hanmi Pharm. Co., Ltd.	2012-04-03	Miscellaneous metabolic drugs	Change in strength and mode of administration/dosage
17	RISENEX-M Tab.	HANLIM PHARM. CO., LTD.	2012-04-03		
18	LETOPRA TAB.20mg	Ahngook Pharm.	2012-06-18	Peptic ulcer drugs	New salts or isomers (first in Korea)

No.	Product name	Company	Approval date	Detailed classification	Remarks
19	Nasaflex Nasal Spray	HANLIM PHARM. CO., LTD.	2012-11-16	Otic and nasal drugs	Change in the type of active substance or compounding ratio
20	Motesoneplus Nasal Spray	Hanmi Pharm. Co., Ltd.	2012-11-16		
21	KanarbPlus Tablet 120/12.5mg	Boryung Pharmaceutical	2013-01-04	Antihypertensives	Change in the type of active substance or compounding ratio
22	KanarbPlus Tablet 60/12.5mg				
23	Olmetan Tab. 22.08mg (olmesartan cilexetil)	JINYANG PHARM CO.,LTD.	2013-01-31	Antihypertensives	New salts or isomers (first in Korea)
24	Olmesin S tab (olmesartan cilexetil)	SK Chemicals			
25	OLMOS-F Tab. 22.08mg (Olmesartan cilexetil)	Ahngook Pharm.			
26	Olmexetil Tablet 22.08mg (Olmesartan cilexetil)	Jeil Pharmaceutical Co., Ltd.			
27	CILOSTAN CR Tab. (Cilostazol)	Korea United Pharm. Inc.	2013-02-28	Miscellaneous blood and body fluid drugs	Change in dosage form, strength or mode of administration/dosage
28	Julian Tab.15mg (Clomipramine HCl)	DongKook Pharmaceutical Co., Ltd.	2013-03-20	Miscellaneous urogenital and anal organ drugs	Added an evidentally different efficacy/effectiveness
29	Nenoma Tablet 15mg (Clomipramine HCl)	Huons Co., Ltd.			
30	Condencia Tab. 15mg (Clomipramine HCl)	CTCBIO INC.			
31	Clojac Tab. (Domipramine hydrochloride)	JINYANG PHARM CO.,LTD.			
32	VOGMET Tablet 0.2/250mg	CJ Cheiljedang Corp. → (name change)HK inno.N	2013-06-17	Antidiabetics	Change in the type of active substance or compounding ratio
33	VOGMET Tablet 0.2/500mg				
34	Bonviva Plus Tablet	Dreampharma Corp.. → (name change) Alvogen Korea Co., Ltd.	2013-07-08	Miscellaneous metabolic drugs	Change in the type of active substance or compounding ratio
35	Levacalm Tab. 20/160mg	LG Life Science→ (name change) LG Chem Ltd.	2013-07-25	Antihypertensives	Change in the type of active substance or compounding ratio
36	Levacalm Tab. 10/160mg				
37	Levacalm Tab. 10/80mg				
38	Zemimet SR Tab. 25/500mg	LG Life Science→ (name change) LG Chem Ltd.	2013-07-25	Antidiabetics	Change in the type of active substance or compounding ratio
39	Dexid Tab 480mg (r-thioctic acid tromethamine)	Bukang Pharm Co.,Ltd	2013-11-21	Miscellaneous metabolic drugs	New salts or isomers (first in Korea)
40	Zemimet SR Tab. 50/1000mg	LG Life Science→ (name change) LG Chem Ltd.	2014-11-07	Antidiabetics	Change in the type of active substance or compounding ratio

No.	Product name	Company	Approval date	Detailed classification	Remarks
41	Sapodifil SR Tablet 300mg (Sarpogrelate hydrochloride)	Alvogen Korea Co., Ltd.	2015-01-23	Miscellaneous blood and body fluid drugs	Change in dosage form, strength and mode of administration/dosage
42	Anpran SR Tablet 300mg (Sapogrelate hydrochloride)	Jeil Pharmaceutical Co., Ltd.			
43	Anpla X-SR Tab 300mg (Sapogrelate hydrochloride)	SK Chemicals			
44	ANPL-ONE SR Tab. 300mg (Sapogrelate hydrochloride)	DAEWOONG PHARMACEUTICAL CO.,LTD.			
45	ANFRADE SR Tablet 300mg (Sarpogrelate hydrochloride)	CJ Healthcare Corp. → (name change)HK inno.N			
46	Pelubi CR Tab. (Pelubiprofen)	Daewon Pharm. Co., Ltd	2015-03-13	Antipyretics, analgesics, and antiinflammatory drugs	Change in dosage form, strength and mode of administration/dosage
47	Tenelia M SR tab. 10/750mg	Handok Inc.	2015-03-31	Antidiabetics	Change in the type of active substance or compounding ratio
48	Tenelia M SR tab. 20/1000mg				
49	Tenelia M SR tab. 10/500mg				
50	EXON SR TABLET (Eperisone hydrochloride)	AJU PHARM CO., LTD.	2015-03-31	Skeletal muscle relaxants	Change in dosage form, strength and mode of administration/dosage
51	Exonin CR tab (Eperisone hydrochloride)	SK Chemicals			
52	Epesine SR Tab. (Eperisone hydrochloride)	Myungmoon Pharm. Co., Ltd.			
53	Nerexone SR Tab. (Eperisone HCl)	Daewon Pharm. Co., Ltd			
54	Eperinal SR Tablet (Eperisone hydrochloride)	Jeil Pharmaceutical Co., Ltd.			
55	Zemimet SR Tab. 50/500mg	LG Life Science→ (name change) LG Chem Ltd.	2015-10-12	Antidiabetics	Change in the type of active substance or compounding ratio
56	Sugamet XR Tablet 2.5/500 mg	DONG-A ST	2015-12-31	Antidiabetics	Change of active substance type or compounding ratio
57	Sugamet XR Tablet 2.5/850 mg				
58	Sugamet XR Tablet 5/1000 mg				

No.	Product name	Company	Approval date	Detailed classification	Remarks
59	Dukarb Tablet 30/5mg	Boryung Pharmaceutical	2016-05-30	Antihypertensives	Change in the type of active substance or compounding ratio
60	Dukarb Tablet 30/10mg				
61	Dukarb Tablet 60/5mg				
62	Dukarb Tablet 60/10mg				
63	Karbpine Tab. 60/5mg	Boryung Biopharma Co., Ltd.	2016-05-31	Antihypertensives	Change in the type of active substance or compounding ratio
64	Karbpine Tab. 60/10mg				
65	Karbpine Tab. 30/5mg				
66	Karbpine Tab. 30/10mg				
67	CANDE AMLO Tablet 16/10mg	SHIN POONG PHARM. CO., LTD.	2016-06-24	Antihypertensives	Change in the type of active substance or compounding ratio
68	CANDE AMLO Tablet 16/5mg				
69	CANDE AMLO Tablet 8/5mg				
70	MACHKHAN Tablet 8/5mg	CJ Healthcare Corp. → (name change)HK inno.N	2016-06-24	Antihypertensives	Change in the type of active substance or compounding ratio
71	MACHKHAN Tablet 16/10mg				
72	MACHKHAN Tablet 16/5mg				
73	Duvimet XR Tab. 0.25/750mg	Chong Kun Dang Pharm.	2016-06-30	Antidiabetics	Change in the type of active substance or compounding ratio
74	Duvimet XR Tab. 0.25/1000mg				
75	Duvimet XR Tab. 0.5/1000mg				
76	GASTIIN CR Tab. (Mosapride citrate dihydrate)	Korea United Pharm. Inc.	2016-06-30	Miscellaneous digestive system drugs	Change in dosage form, strength and mode of administration/dosage
77	Zemimet SR Tab. 25/1000mg	LG Life Science→ (name change) LG Chem Ltd.	2016-06-30	Antidiabetics	Change in the type of active substance or compounding ratio
78	Duvimet XR Tab. 0.25/500mg	Chong Kun Dang Pharm.	2016-09-01	Antidiabetics	Change in the type of active substance or compounding ratio
79	LIPORAXEL SOLUTION (PACLITAXEL)	DAEHWA PHARMACEUTICAL., LTD.	2016-09-09	anti-tumor drugs	New route of administration
80	Safrep Solution	CTCBIO INC.	2016-10-06	X-ray contrast agent	Change in the type of active substance or compounding ratio
81	Duocolon Solution	Alvogen Korea Co., Ltd.	2016-10-06	X-ray contrast agent	Change in the type of active substance or compounding ratio
82	Coolipa Sol.	Ahngook Pharm.	2016-10-06	X-ray contrast agent	Change in the type of active substance or compounding ratio
83	Surfolase CR Tablet (Acebrophylline)	Hyundai Pharm	2017-02-24	Miscellaneous respiratory organ drugs	Change in dosage form, strength and mode of administration/dosage
84	LEVOTICS CR Tab. (Levodropropizine)	Korea United Pharm. Inc.	2017-04-12	Antitussive expectorants	Change in dosage form, strength and mode of administration/dosage

No.	Product name	Company	Approval date	Detailed classification	Remarks
85	Levocare CR Tablets (Levodropropizine)	Kwangdong Pharm, Ltd.	2017-04-12	Antitussive expectorants	Change in dosage form, strength and mode of administration/dosage
86	Neotuss SR Tab. (Levodropropizine)	JW shinyak	2017-04-12	Antitussive expectorants	Change in dosage form, strength and mode of administration/dosage
87	Amosartan Plus Tab. 5/50/12.5mg	Hanmi Pharm. Co., Ltd.	2017-06-29	Antihypertensives	Change in the type of active substance or compounding ratio
88	Amosartan Plus Tab. 5/100/12.5mg				
89	Amosartan Plus Tab. 5/100/25mg				
90	TWOTOPSPLUS Tab. 40/5/12.5 mg	ILDONG PHARMACEUTICAL CO., LTD.	2017-07-25	Antihypertensives	Change in the type of active substance or compounding ratio
91	TWOTOPSPLUS Tab. 80/5/12.5 mg				
92	TWOTOPSPLUS Tab. 80/10/12.5 mg				
93	TWOTOPSPLUS Tab. 80/10/25 mg				
94	BELION CR Tab. (Bepotastine salicylate)	HANLIM PHARM. CO., LTD.	2018-07-30	Antihistamines	Change in dosage form, strength and mode of administration/dosage
95	Tari-S CR tab. (Bepotastine salicylate)	Sam Chun Dang Pharm. Co.,Ltd.			
96	Beposta SR Tab. (Bepotastine salicylate)	Daewon Pharm. Co., Ltd			
97	Bepo-Q SR Tab. (Bepotastine salicylate)	Kwangdong Pharm, Ltd.			
98	Bepotan SR Tab. (Bepotastine salicylate)	DongKook Pharmaceutical Co., Ltd.			
99	Beporine SR Tab. (Bepotastine salicylate)	SAM-A PHARM. CO., LTD.			
100	CLEANVIEWAL Powder	Taejoon Pharmaceutical Co., Ltd.	2019-01-31	X-ray contrast agent	Change in the type of active substance or compounding ratio
101	STAFEN Cap.	HANLIM PHARM. CO., LTD.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
102	Neustatin-Duo Capsule	Samjin Pharmaceutical Co., Ltd.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
103	Pitalone-F Cap.	DongKook Pharmaceutical Co., Ltd.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
104	Pevaro-F Cap.	Ahngook Pharm.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
105	Liloufen Cap.	GL Pharma	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
106	Uptava Cap.	Daewon Pharm. Co., Ltd	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
107	Lipestin Cap.	Korea Prime Pharm. Co., Ltd.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
108	PF Capsule.	Dong Kwang Pharm. Co.,Ltd.	2019-04-03	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio

No.	Product name	Company	Approval date	Detailed classification	Remarks
109	Orafang Tab.	Pharmbio Korea Inc.	2019-04-11	X-ray contrast agent	Change in the type of active substance or compounding ratio
110	True Set Tablet 40/5/12.5mg	Yuhan Corporation	2019-08-23	Antihypertensives	Change in the type of active substance or compounding ratio
111	True Set Tablet 80/5/12.5mg				
112	True Set Tablet 80/5/25mg				
113	OnePrep 1.38 powder	Kungang Pharmaceuticals	2020-04-10	X-ray contrast agent	Change in the type of active substance or compounding ratio
114	Codaewon S syrup	Daewon Pharm. Co., Ltd	2020-07-15	Antitussive expectorants	Change in the type of active substance or compounding ratio
115	Recomid SR tablet(Rebamipide)	Yuhan Corporation	2020-12-16	Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage
116	Mucotect SR Tab.	GC Pharma	2020-12-16	Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage
117	MUCOTRA SR tab	DAEWOONG PHARMACEUTICAL CO.,LTD.	2020-12-16	Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage
118	Bidreba SR 150mg	Daewon Pharm. Co., Ltd	2020-12-16	Peptic ulcer drugs	Change in dosage form, strength and mode of administration/dosage
119	Atromega combigel soft capsule	Korea United Pharm Inc.	2021-01-21	Antiarteriosclerotic agents	Change in the type of active substance or compounding ratio
120	LivaloZet Tablet 2/ 10mg	JW Pharmaceutical	2021-07-28	Antiarteriosclerotic agents	Change in the type of active substance or compounding ratio
121	LivaloZet Tablet 2/ 10mg				
122	Donerion Patch 87.5mg (Donepezil)	Celltrion Pharm, Inc.	2021-11-05	Miscellaneous central nervous system drugs	New route of administration
123	Donerion Patch 175mg (Donepezil)				
124	Donhesive Patch 87.5mg (Donepezil)	ICURE Pharmaceutical Inc.	2021-11-05	Miscellaneous central nervous system drugs	New route of administration
125	Donhesive Patch 175mg (Donepezil)				
126	Dukarb Plus Tab. 30/5/12.5 mg	Boryung Co., Ltd.	2022-03-31	Antihypertensives	Change in the type of active substance or compounding ratio
127	Dukarb Plus Tab. 60/10/12.5 mg	Boryung Co., Ltd.	2022-03-31	Antihypertensives	Change in the type of active substance or compounding ratio
128	Dukarb Plus Tab. 60/10/25 mg	Boryung Co., Ltd.	2022-03-31	Antihypertensives	Change in the type of active substance or compounding ratio
129	Dukarb Plus Tab. 60/5/12.5 mg	Boryung Co., Ltd.	2022-03-31	Antihypertensives	Change in the type of active substance or compounding ratio
130	Dukarb Plus Tab. 60/5/25 mg	Boryung Co., Ltd.	2022-06-10	Antihypertensives	Change in the type of active substance or compounding ratio
131	REBAEYE 2%(rebamipide)	Kukje Pharm.	2022-06-16	Ophthalmic drugs	New route of administration
132	RevaK Eyedrops (rebamipide)	Sam Il	2022-06-16	Ophthalmic drugs	New route of administration

No.	Product name	Company	Approval date	Detailed classification	Remarks
133	Zemidapa Tablet	LG Chem	2022-06-21	Antidiabetics	Change in the type of active substance or compounding ratio
134	AFEXON Tab.	Aju Pharm	2022-09-14	Antipyretics, analgesics, and anti inflammatory drugs	Change in the type of active substance or compounding ratio
135	Sugadapa Tablet	DONG-A ST	2023-03-10	Antidiabetics	Change in the type of active substance or compounding ratio
136	Duvimet S XR Tab.0.25/50/750mg	Chong Kun Dang Pharm.	2023-05-02	Antidiabetics	Change in the type of active substance or compounding ratio
137	Duvimet S XR Tab. 0.25/50/1000 mg	Chong Kun Dang Pharm.	2023-05-02	Antidiabetics	Change in the type of active substance or compounding ratio
138	Duvimet S XR Tab. 0.5/100/1000 mg	Chong Kun Dang Pharm.	2023-05-02	Antidiabetics	Change in the type of active substance or compounding ratio
139	Duvimet S XR Tab.0.25/50/500mg	Chong Kun Dang Pharm.	2023-05-02	Antidiabetics	Change in the type of active substance or compounding ratio
140	Luminomark inj. (Indocyanine Green)	Hanlim Pharm. Co., Ltd	2023-05-11	Drugs that are not specifically classified and are not therapeutic in nature	Distinctly different efficacy/effectiveness addition
141	Duvie S Tab.0.5/100mg	Chong Kun Dang Pharm.	2023-06-09	Antidiabetics	Change in the type of active substance or compounding ratio
142	Envlomet SR Tab. 0.3/1000mg(Enavogliflozin, Metformin hydrochloride)	Daewoong Pharmaceuticals	2023-06-13	Antidiabetics	Change in the type of active substance or compounding ratio
143	Layla DS Tab.	PMG Pharm. Co., Ltd.	2023-08-09	Antipyretics, analgesics, and antiinflammatory drugs	Change in the type of active substance or compounding ratio
144	TRUBUDDY tablet 10/15mg (Dapagliflozin,Pioglitazone)	Boryung Co., Ltd.	2023-08-29	Antidiabetics	Change in the type of active substance or compounding ratio
145	TRUBUDDY tablet 10/30mg (Dapagliflozin,Pioglitazone)	Boryung Co., Ltd.	2023-08-29	Antidiabetics	Change in the type of active substance or compounding ratio
146	Sugatree XR tablet 5/10/1000mg(Evogliptin,Dapagliflozin, Metformin hydrochloride)	DONG-A ST	2023-10-30	Antidiabetics	Change in the type of active substance or compounding ratio
147	Aprovasc Tab. 150/10mg (Irbesartan, Amlodipine besylate)	Handok Inc.	2023-11-28	Antihypertensives	Change in the type of active substance or compounding ratio
148	Aprovasc Tab. 300/5mg (Irbesartan, Amlodipine besylate)	Handok Inc.	2023-11-28	Antihypertensives	Change in the type of active substance or compounding ratio
149	Aprovasc Tab. 150/5mg (Irbesartan, Amlodipine besylate)	Handok Inc.	2023-11-28	Antihypertensives	Change in the type of active substance or compounding ratio

※ Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr

2.4. Approval Status of Drugs Requiring Data Submission

Drugs requiring data submission refer to drugs that are not new drugs, but require safety and efficacy review, such as ▲Drugs that contain new salts (isomers) as an active substance, ▲Drugs belonging to new pharmacological class, ▲New composition of active substances, or changes only in strength, ▲Drugs with new route of administration, ▲Drugs with administration/ dosage, ▲New dosage form (same administration route), etc.

Among the drugs requiring data submission (excluding 15 incrementally modified drug items), 366 items (97.6%) were manufactured and 9 items (3.4%) were imported items, manufactured items account for the large proportion. By approval review type, drugs with a new salts or isomers accounted for the largest portion (50.4%, 189 items), followed by drugs with new composition or changes in strength (35.5%, 133 items) (refer to Table 33).

Table 33. Drugs Requiring Data Submission Approved in 2023

Review Type of Drugs Requiring Data Submission		No. of Approved Items	
Drugs containing new salts, isomers, low molecular weight synthetic peptides, etc. as active ingredients		189(50.4%)	
New pharmacologic class		1(0.3%)	
New composition of active substance or change only in strength	133 (35.5%)	New composition	92(24.5%)
		Change in strength	41(11.0%)
New route of administration		0(0.0%)	
New administration/ dosage		2(0.5%)	
Enzymes, yeasts and microbial agents of novel origin (pharmacologically equivalent)		0(0.0%)	
New dosage form (same route of administration)		50(13.3%)	
Total		375	

* Excluding incrementally modified drugs (drugs that require data submission)

2.4.1. New Salt or Isomer Drugs

The chemical drugs with new salts or isomers were approved as 189 manufactured items, of which 87 items (46.0%) were developed from sitagliptin phosphate hydrate, an approved anti-, into sitagliptin hydrochloride and 30 items (15.9%) were developed from dapagliflozin propanediol hydrate as new salts (anhydrous lactose hydrate, L-proline). Anti-diabetics accounted for the largest proportion (61.9%) followed by 64 items (33.9%) which were developed from amlodipine besylate for hypertension as s-amlodipine besylate 2.5 hydrate.

In addition, 7 items in which tenofovir alafenamide hemifumarate for the liver disease drug, was changed to a new salt (succinate, hemitartrate, hemimalate, etc.), were approved, and 1 item was approved for the development of L-carnitine orotate into L-carnitine napadisilate (refer to Table 34).

Table 34. Drugs Requiring Data Submission with New Salt or New Isomer Approved in 2023

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
1	Manufactured	GL SitaMet XR tab. 50/750mg	GL Pharma	2023-01-02	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
2	Manufactured	Janulitin Combi XR Tab. 50/750mg	Daewon Pharmaceutical Co., Ltd.	2023-01-02	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
3	Manufactured	TRUSita M XR Tab. 50/750 mg (sitagliptin, metformin)	Boryung Co., Ltd.	2023-01-02	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
4	Manufactured	Tecavir-D Tablet (Tenofovir alafenamide)	Jeil Pharmaceutical Co., Ltd.	2023-01-04	Liver disease agents	Tenofovir alafenamide hemifumarate → Tenofovir alafenamide
5	Manufactured	S-karb Tab. 30/2.5mg	DONGKOO Bio&Pharma Co., Ltd.	2023-01-05	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
6	Manufactured	S-karb Tab. 60/2.5mg	DONGKOO Bio&Pharma Co., Ltd.	2023-01-05	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
7	Manufactured	S-karb Tab. 60/5mg	DONGKOO Bio&Pharma Co., Ltd.	2023-01-05	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
8	Manufactured	Forxigly Duo Extended Release Tab 10/1000mg	Sinil Pharmaceutical	2023-01-05	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
9	Manufactured	Kuhnkarb Tab. 30/2.5mg	Kuhnil biopharm. Co.,Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
10	Manufactured	Kuhnkarb Tab. 60/2.5mg	Kuhnil biopharm. Co.,Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
11	Manufactured	Kuhnkarb Tab. 60/5mg	Kuhnil biopharm. Co.,Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
12	Manufactured	GlifloM XR tab. 10/1000	Daewoopharm	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
13	Manufactured	Dapalizin Duo SR Tab 10/1000mg	GUJU Pharm Co., Ltd.	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
14	Manufactured	Dapa-L Duo XR Tablet 10/1000mg	HLB Pharmaceutical Co., Ltd.	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
15	Manufactured	DAPAKHANMET XR Tab. 10/1000mg	Kyongbo pharma	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
16	Manufactured	Dapozin M XR Tab. 10/1000mg	SAMJIN PHARM.CO.,LTD	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
17	Manufactured	Daflo M XR tab. 10/1000mg	Dongkwang Pharm. Co., Ltd.	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
18	Manufactured	Daflozinduo XR tab. 10/1000mg	PharmGen Science, Inc.	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
19	Manufactured	Dangduo XR Tab.10/1000mg	HUTECS KOREA PHARMACEUTICAL CO.,LTD.	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
20	Manufactured	DurabTab.30/2.5mg (Fimasartan potassium, S-amlodipine)	NEXPHARM KOREA	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
21	Manufactured	DurabTab.60/2.5mg (Fimasartan potassium, S-amlodipine)	NEXPHARM KOREA CO., LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
22	Manufactured	DurabTab.60/5mg (Fimasartan potassium, S-amlodipine)	NEXPHARM KOREA CO., LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
23	Manufactured	Duallow tab. 30/2.5mg	Union Korea Pharm Co. LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
24	Manufactured	Duallow tab. 60/2.5mg	Union Korea Pharm Co. LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
25	Manufactured	DUALTERA Tablet 30/2.5mg	JW sinyak	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
26	Manufactured	DUALTERA Tablet 60/5mg	JW sinyak	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
27	Manufactured	Duyzen Tab. 30/2.5mg (Fimasartan Potassium Trihydrate/S-Amlodipine besylate)	CTCBIO INC.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
28	Manufactured	Duyzen Tab. 60/2.5mg (Fimasartan Potassium Trihydrate/S-Amlodipine besylate)	CTCBIO INC.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
29	Manufactured	Duyzen Tab. 60/5mg (Fimasartan Potassium Trihydrate/S-Amlodipine besylate)	CTCBIO INC.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
30	Manufactured	Dukanagen Tab. 30/2.5mg	THERAGEN ETEX CO., LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
31	Manufactured	Dukanagen Tab. 60/2.5mg	THERAGEN ETEX CO., LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
32	Manufactured	DUKARNOVA TAB. 30/2.5mg	Daewoong Bio Inc.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
33	Manufactured	DUKARNOVA TAB. 60/2.5mg	Daewoong Bio Inc.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
34	Manufactured	DUKARNOVA TAB. 60/5mg	Daewoong Bio Inc.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
35	Manufactured	Dukadipine 30/2.5mg	IL HWA CO.,LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
36	Manufactured	Dukadipine 60/2.5mg	IL HWA CO.,LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
37	Manufactured	Dukar-LB Tab. 30/2.5mg	HLB Pharmaceutical Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
38	Manufactured	Dukar-LB Tablet 60/2.5mg	HLB Pharmaceutical Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
39	Manufactured	Dukar-LB Tablet 60/5mg	HLB Pharmaceutical Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
40	Manufactured	DukarM Tab. 30/2.5mg	MOTHER'S PHARMACEUTICAL	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
41	Manufactured	DukarM Tab. 60/2.5mg	MOTHER'S PHARMACEUTICAL	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
42	Manufactured	DukarM Tab. 60/5mg	MOTHER'S PHARMACEUTICAL	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
43	Manufactured	Dukaforge Tab. 30/2.5mg	Whan In Pharm Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
44	Manufactured	Dukaforge Tab. 60/2.5mg	Whan In Pharm Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
45	Manufactured	Dukaforge Tab. 60/5mg	Whan In Pharm Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
46	Manufactured	Dukafin Tab. 30/2.5mg	Aprogen Biologics Inc.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
47	Manufactured	Dukafin Tab. 60/2.5mg	Aprogen Biologics Inc.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
48	Manufactured	Dukafin Tab. 60/5mg	Aprogen Biologics Inc.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
49	Manufactured	Ducor tab. 30/2.5mg	Neo Bio Korea Pharm. Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
50	Manufactured	Ducor tab. 60/2.5mg	Neo Bio Korea Pharm. Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
51	Manufactured	Ducor tab. 60/5mg	Neo Bio Korea Pharm. Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
52	Manufactured	Sugapa Duo ER Tab. 10/1000mg	UNIMED PHARM INC.	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
53	Manufactured	Adikarb Tab. 30/2.5mg	Korea Global Pharm Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
54	Manufactured	Adikarb Tab. 60/2.5mg	Korea Global Pharm Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
55	Manufactured	Adikarb Tab. 60/5mg	Korea Global Pharm Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
56	Manufactured	Amdikarb Q Tab. 30/2.5mg	Young Poong Pharmaceutical Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
57	Manufactured	Amdikarb Q Tab. 60/2.5mg	Young Poong Pharmaceutical Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
58	Manufactured	Amdikarb Q Tab. 60/5mg	Young Poong Pharmaceutical Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
59	Manufactured	S-forga Duo XR Tab. 10/100mg	Sam-chun-dang Pharm	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
60	Manufactured	Yungjindadu XR 10/1000mg	YUNGJIN PHARM. CO.,LTD	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
61	Manufactured	Genxigamet SR tablet	Alvogen Korea Co., Ltd.	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
62	Manufactured	FOXIFLE DUO XR TAB. 10/1000 mg	Dongwha Pharm. Co., Ltd.	2023-01-06	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
63	Manufactured	Fimaduet Tab. 30/2.5mg	KOREA PRIME PHARM CO.,LTD	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
64	Manufactured	Fimaduet Tab. 60/2.5mg	KOREA PRIME PHARM CO.,LTD	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
65	Manufactured	Fima Duo Tab. 30/2.5mg	SAMJIN PHARM.CO.,LTD	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
66	Manufactured	Fima Duo Tab. 60/2.5mg	SAMJIN PHARM.CO.,LTD	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
67	Manufactured	Fima Duo 60/5mg	SAMJIN PHARM.CO.,LTD	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
68	Manufactured	Fimalopine Tab. 30/2.5mg	Binex Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
69	Manufactured	Fimalopine Tab. 60/2.5mg	Binex Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
70	Manufactured	Fimalopine Tab. 60/5mg	Binex Co., Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
71	Manufactured	Fimasab Tab. 30/2.5mg	IL SUNG IS CO., LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
72	Manufactured	Fimasab Tab. 60/2.5mg	IL SUNG IS CO., LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
73	Manufactured	Fimasab Tab. 60/5mg	IL SUNG IS CO., LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
74	Manufactured	Fima-S Tab. 60/2.5mg	Dongkook Pharmaceutical Co.,Ltd.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
75	Manufactured	FIMARTEN Tab. 30/2.5mg	AJU PHARM CO., LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
76	Manufactured	FIMARTEN Tab. 60/2.5mg	AJU PHARM CO., LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
77	Manufactured	FIMARTEN Tab. 60/5mg	AJU PHARM CO., LTD.	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
78	Manufactured	Pincarb.Tab.30/2.5mg (Fimasartan Potassium, S-Amlodipine)	Edenpharma	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
79	Manufactured	Pincarb.Tab.60/2.5mg (Fimasartan Potassium, S-Amlodipine)	Edenpharma	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
80	Manufactured	Pincarb.Tab.60/5mg (Fimasartan Potassium, S-Amlodipine)	Edenpharma	2023-01-06	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
81	Manufactured	Tenofobell-A Tab. (Tenofovir alafenamide succinate)	Chong Kun Dang Pharm.	2023-01-10	Liver disease agents	Tenofovir alafenamide hemifumarate → Tenofovir alafenamide succinate
82	Manufactured	Vemliver tab	Daewoong Pharmaceuticals	2023-01-12	Liver disease agents	Tenofovir alafenamide hemifumarate → Tenofovir alafenamide succinate
83	Manufactured	Fima-S Tab. 30/2.5mg	Dongkook Pharmaceutical Co.,Ltd.	2023-01-31	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
84	Manufactured	Fima-S Tab. 60/5mg	Dongkook Pharmaceutical Co.,Ltd.	2023-01-31	Antihypertensives	Amlodipine besylate → S-amlodipine besylate 2.5 hydrate
85	Manufactured	Sitaviance Duo XR Tablet 100/1000mg	Daehwa Pharmaceutical Co., Ltd.	2023-02-16	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
86	Manufactured	Sitaviance Duo XR Tablet 50/1000mg	Daehwa Pharmaceutical Co., Ltd.	2023-02-16	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
87	Manufactured	Sitaviance Duo XR Tablet 50/500mg	Daehwa Pharmaceutical Co., Ltd.	2023-02-16	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
88	Manufactured	Glositaformin SR Tab. 100/1000mg	Korea Global Pharm Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
89	Manufactured	Glositaformin SR Tab. 50/1000mg	Korea Global Pharm Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
90	Manufactured	Glositaformin SR Tab. 50/500mg	Korea Global Pharm. Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
91	Manufactured	Danumet XR Tab. 100/1000mg	KS Pharm. Inc.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
92	Manufactured	Danumet XR Tab. 50/1000mg	KS Pharm. Inc.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
93	Manufactured	Danumet XR Tab. 50/500mg	KS Pharm. Inc.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
94	Manufactured	Sidi 4M XR Tab. 100/1000mg	Dongkwang Pharm. Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
95	Manufactured	Sidi 4M XR Tab. 50/1000mg	Dongkwang Pharm. Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
96	Manufactured	Sidi 4M XR Tab. 50/500mg	Dongkwang Pharm. Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
97	Manufactured	Sitadual XR 100/1000 tab.	Hyundai Pharm Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
98	Manufactured	Sitadual XR 50/1000 tab.	Hyundai Pharm Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
99	Manufactured	Sitadual XR 50/500 tab.	Hyundai Pharm Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
100	Manufactured	Sitaroutine Duo XR tab. 100/1000mg	SHIN POONG PHARM. CO., LTD	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
101	Manufactured	Sitaroutine Duo XR tab. 50/1000mg	SHIN POONG PHARM. CO., LTD	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
102	Manufactured	Sitaroutine Duo XR tab. 50/500mg	SHIN POONG PHARM. CO., LTD	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
103	Manufactured	Sitatidine Duo XR Tab. 100/1000mg	TDS Pharm Co.,Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
104	Manufactured	Sitatidine Duo XR Tab. 50/1000mg	TDS Pharm Co.,Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
105	Manufactured	Sitatidine Duo XR Tab. 50/500mg	TDS Pharm Co.,Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
106	Manufactured	Janugliptinduo XR Tab. 100/1000mg	Cires Pharmaceutical Inc.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
107	Manufactured	Janugliptinduo XR Tab. 50/1000mg	Cires Pharmaceutical Inc.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
108	Manufactured	Janugliptinduo XR Tab. 50/500mg	Cires Pharmaceutical Inc.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
109	Manufactured	Januglu M XR Tab. 100/1000mg	Sam-chun-dang Pharm	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
110	Manufactured	Januglu M XR Tab. 50/1000mg	Sam-chun-dang Pharm	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
111	Manufactured	Januglu M XR Tab. 50/500mg	Sam-chun-dang Pharm	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
112	Manufactured	Janudi-M XR Tab.100/1000mg	KUKJE pharmaceutical co., ltd	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
113	Manufactured	Janudi-M XR Tab.50/1000mg	KUKJE pharmaceutical co., ltd	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
114	Manufactured	Janudi-M XR Tab.50/500mg	KUKJE pharmaceutical co., ltd	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
115	Manufactured	Janustinmet XR Tab. 100/1000mg	Kyongbo pharma	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
116	Manufactured	Janustinmet XR Tab. 50/1000mg	Kyongbo pharma	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
117	Manufactured	Janustinmet XR Tab. 50/500mg	Kyongbo pharma	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
118	Manufactured	JANUATIN Duo XR Tab. 100/1000mg	PharmGen Science, Inc.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
119	Manufactured	JANUATIN Duo XR Tab. 50/1000mg	PharmGen Science, Inc.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
120	Manufactured	JANUATIN Duo XR Tab. 50/500mg	PharmGen Science, Inc.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
121	Manufactured	Huglia M XR Tablet 100/1000mg	Huons Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
122	Manufactured	Huglia M XR Tablet 50/1000mg	Huons Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
123	Manufactured	Huglia M XR Tablet 50/500mg	Huons Co., Ltd.	2023-02-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
124	Manufactured	Sitaviance Duo Tablet 50/1000mg	Daehwa Pharmaceutical Co., Ltd.	2023-03-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
125	Manufactured	Sitaviance Duo Tablet 50/500mg	Daehwa Pharmaceutical Co., Ltd.	2023-03-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
126	Manufactured	Sitaviance Duo Tablet 50/850mg	Daehwa Pharmaceutical Co., Ltd.	2023-03-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
127	Manufactured	Glositaformin Tab. 50/1000mg	Korea Global Pharm. Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
128	Manufactured	Glositaformin Tab. 50/500mg	Korea Global Pharm. Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
129	Manufactured	Glositaformin Tab. 50/850mg	Korea Global Pharm. Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
130	Manufactured	Danumet Tab. 50/1000mg	KS Pharm. Inc.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
131	Manufactured	Danumet Tab. 50/500mg	KS Pharm. Inc.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
132	Manufactured	Danumet Tab. 50/850mg	KS Pharm. Inc.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
133	Manufactured	Sidi 4M Tab. 50/1000mg	Dongkwang Pharm. Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
134	Manufactured	Sidi 4M Tab. 50/500mg	Dongkwang Pharm. Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
135	Manufactured	Sidi 4M Tab. 50/850mg	Dongkwang Pharm. Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
136	Manufactured	Sitadual 50/1000 tab.	Hyundai Pharm Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
137	Manufactured	Sitadual 50/500 tab.	Hyundai Pharm Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
138	Manufactured	Sitadual 50/850 tab.	Hyundai Pharm Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
139	Manufactured	Shinpoong sitaplus tab. 50/1000mg	SHIN POONG PHARM. CO., LTD	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
140	Manufactured	Shinpoong sitaplus tab. 50/500mg	SHIN POONG PHARM. CO., LTD	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
141	Manufactured	Shinpoong sitaplus tab. 50/850mg	SHIN POONG PHARM. CO., LTD	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
142	Manufactured	Sitatidine duo Tab. 50/1000mg	TDS Pharm Co.,Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
143	Manufactured	Sitatidine duo Tab. 50/500mg	TDS Pharm Co.,Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
144	Manufactured	Sitatidine duo Tab. 50/850mg	TDS Pharm Co.,Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
145	Manufactured	Janugliptinduo Tab. 50/1000mg	Cires Pharmaceutical Inc.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
146	Manufactured	Janugliptinduo Tab. 50/500mg	Cires Pharmaceutical Inc.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
147	Manufactured	Janugliptinduo Tab. 50/850mg	Cires Pharmaceutical Inc.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
148	Manufactured	Janudi-M Tab.50/1000mg	KUKJE pharmaceutical co., ltd	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
149	Manufactured	Janudi-M Tab.50/500mg	KUKJE pharmaceutical co., ltd	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
150	Manufactured	Janudi-M Tab.50/850mg	KUKJE pharmaceutical co., ltd	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
151	Manufactured	JANUSMET TAB. 50/1000mg	Kyongbo pharma	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
152	Manufactured	JANUSMET TAB. 50/500mg	Kyongbo pharma	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
153	Manufactured	JANUSMET TAB. 50/850mg	Kyongbo pharma	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
154	Manufactured	JANUATIN Duo Tab. 50/1000mg	PharmGen Science, Inc.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
155	Manufactured	JANUATIN Duo Tab. 50/500mg	PharmGen Science, Inc.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
156	Manufactured	JANUATIN Duo Tab. 50/850mg	PharmGen Science, Inc.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
157	Manufactured	Huglia M Tablet 50/1000 mg	Huons Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
158	Manufactured	Huglia M Tablet 50/500 mg	Huons Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
159	Manufactured	Huglia M Tablet 50/850 mg	Huons Co., Ltd.	2023-03-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
160	Manufactured	Ganelid Tab.	HUTECS KOREA PHARMACEU-TICAL CO,LTD.	2023-03-15	Liver disease agents	Tenofovir alafenamide hemifumarate → Tenofovir alafenamide hemimalate
161	Manufactured	Vemlino Tablet	Samil Pharm. Co., Ltd.	2023-03-15	Liver disease agents	Tenofovir alafenamide hemifumarate → Tenofovir alafenamide hemimalate
162	Manufactured	Alfoterin Tablet(Tenofovir Alafenamide Hemi L-(-)-Malate)	Dongkook Pharmaceutical Co.,Ltd.	2023-03-15	Liver disease agents	Tenofovir alafenamide hemifumarate → Tenofovir alafenamide hemimalate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
163	Manufactured	TAFLEAD Tab.	SAMJIN PHARM.CO.,LTD	2023-03-15	Liver disease agents	Tenofovir alafenamide hemifumarate → Tenofovir alafenamide hemimalate
164	Manufactured	Godex Max Tab.	Celltrion Pharm, Inc.	2023-05-10	Liver disease agents	L-Carnitine orotate → L-Carnitine Naphadisilicate
165	Manufactured	Sita plus tablet 50/1000mg (Sitagliptin, Metformin))	CMG Pharmaceutical Co., Ltd	2023-06-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
166	Manufactured	Sita Plus tablet 50/500mg(Sitagliptin, Metformin)	CMG Pharmaceutical Co., Ltd	2023-06-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
167	Manufactured	Sita plus tablet 50/850mg(Sitagliptin, Metformin)	CMG Pharmaceutical Co., Ltd	2023-06-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
168	Manufactured	Januglu M Tab. 50/1000mg	Sam-chun-dang Pharm	2023-06-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
169	Manufactured	Januglu M Tab. 50/500mg	Sam-chun-dang Pharm	2023-06-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
170	Manufactured	Januglu M Tab. 50/850mg	Sam-chun-dang Pharm	2023-06-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
171	Manufactured	Dapazin-S duo Tab. 10/100mg (Dapagliflozin, Sitagliptin)	KyungDong Pharm. Co., Ltd.	2023-06-15	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
172	Manufactured	Forxigly Duo Extended Release Tablet 10/500mg	Sinil Pharm	2023-06-16	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
173	Manufactured	Sita Plus extended release tablet 100/1000mg(Sitagliptin ,Metformin)	CMG Pharmaceutical Co., Ltd	2023-06-20	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
174	Manufactured	Sita plus extended release tablet 50/1000mg(Sitagliptin, Metformin)	CMG Pharmaceutical Co., Ltd	2023-06-20	Miscellaneous circulatory system drugs	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate
175	Manufactured	Sita plus extended release 50/500mg (Sitagliptin,Metformin)	CMG Pharmaceutical Co., Ltd	2023-06-20	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
176	Manufactured	GliflоM XR tab. 10/500mg	Daewoo pharm	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
177	Manufactured	Dapalizin Duo SR Tab. 10/500mg	GUJU Pharm Co., Ltd.	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
178	Manufactured	Dapa-L Duo XR tablet 10/500mg	HLB Pharmaceutical Co., Ltd.	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
179	Manufactured	DAPAKHANMET XR Tab. 10/500mg	Kyongbo pharma	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
180	Manufactured	Dapozin M XR Tab. 10/500mg	SAMJIN PHARM.CO., LTD	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
181	Manufactured	Daflo M XR tab. 10/500mg	Dongkwang Pharm. Co., Ltd.	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
182	Manufactured	Daflozinduo XR tab. 10/500mg	PharmGen Science, Inc.	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
183	Manufactured	Dangduo XR Tab. 10/500 mg	HUTECS KOREA PHARMACEUTICAL CO.,LTD.	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
184	Manufactured	Sugapa Duo ER Tab. 10/500mg	UNIMED PHARM INC.	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
185	Manufactured	S-forga Duo XR Tab. 10/500mg	Sam-chun-dang Pharm	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
186	Manufactured	Yungjindadu XR Tab. 10/500mg	YUNGJIN PHARM. CO.,LTD	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
187	Manufactured	Genxigamet SR Tab. 10/500mg	Alvogen Korea Co., Ltd.	2023-06-21	Miscellaneous circulatory system drugs	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
188	Manufactured	FOXIFLE DUO XR TAB. 10/500 mg	Dongwha Pharm. Co., Ltd.	2023-06-21	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture
189	Manufactured	Husiglo Tab. (Dapagliflozin,Sitagliptin)	Huons Co., Ltd.	2023-06-29	Antidiabetics	Dapagliflozin propanediol hydrate → Dapagliflozin anhydrous lactose mixture

* Detailed approval information (efficacy/effectiveness, administration/dosage and precautions for use) is available at http://nedrug.mfds.go.kr

2.4.2. Drugs in New Therapeutic Class

One drug with new therapeutic class was approved and it was a imported item. It was approved for the reduction of recurrence of overt hepatic encephalopathy in patients 18 years of age and older, which was previously indicated for the treatment of diarrheal syndrome caused by acute intestinal infections with gram-positive and gram-negative bacteria (refer to Table 35).

Table 35. Drugs Requiring Data Submission in New Therapeutic Class Approved in 2023

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Efficacy/ Effectiveness
1	Imported	Tixtar tablet (Rifaximin)	SAMJOH PHARM CO., LTD.	2023-08-07	Liver disease agents	Reducing recurrence of overt hepatic encephalopathy in patients 18 years and older

2.4.3. Drugs with New Composition of Active Ingredient or Change Only in Strength

92 drugs with new composition (91 manufactured items and 1 imported item) were approved, of which 33 (35.9%) were the circulatory system drugs, including antihypertensive drugs and antiarteriosclerotic agents, 28 (30.4%) for diabetes, 17 (18.5%) for antipyretic, analgesic, and anti-inflammatory drugs, and 10 (10.9%) for peptic ulcer, accounting for the majority. For the new combination drugs, 19 (20.7%) were approved for hyperlipidemia and 10 (10.8%) for hypertension/hyperlipidemia. When sorted by their ingredient, 20 (21.7%) combination products containing ezetimibe (hypertension/ hyperlipidemia or hyperlipidemia) accounted for nearly two-thirds (60.6%) of the circulatory system drugs with new composition approved in 2023 and 28 anti-diabetics with new composition were mostly combination drugs (26) containing sitagliptin phosphate hydrate or dapagliflozin propanediol hydrate (refer to Table 36).

41 items with changes in strength were approved (38 manufactured and 3 imported items), including 19 for the circulatory system, 8 for anticoagulants, 3 for protein amino acids preparations, 3 for anti-diabetics, 4 for peptic ulcers, 2 for the central nervous system, 1 for psychiatry, and 1 for parasitic skin diseases, suggesting that drugs with different efficacy were approved following changes in strength (refer to Table 37).

Table 36. Drugs Requiring Data Submission with New Composition Approved in 2023

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
1	Manufactured	NewRanso-X tab. 30/600mg	Union Korea Pharm Co. LTD.	2023-01-09	Peptic ulcer drugs	Lansoprazole, precipitated calcium carbonate
2	Manufactured	Lansatone Duo Tab. 30/600mg	Hana Pharm. Co., Ltd.	2023-01-09	Peptic ulcer drugs	Lansoprazole, precipitated calcium carbonate
3	Manufactured	RansoDuo Tab. 30/600mg	GUJU Pharm Co., Ltd.	2023-01-09	Peptic ulcer drugs	Lansoprazole, precipitated calcium carbonate
4	Manufactured	Lanso & Tab. 30/600mg	Yu&life sciences	2023-01-09	Peptic ulcer drugs	Lansoprazole, precipitated calcium carbonate
5	Manufactured	Lanstar Tab. 30/600mg	Myungmoon Pharm. Co., Ltd.	2023-01-09	Peptic ulcer drugs	Lansoprazole, precipitated calcium carbonate
6	Manufactured	Lantanduo 30/600mg	UNIMED PHARM INC.	2023-01-09	Peptic ulcer drugs	Lansoprazole, precipitated calcium carbonate
7	Manufactured	Rosuvamibe 10/2.5mg	YUHAN Coporation	2023-02-07	Antiarterioscle-rotic agents	Ezetimibe (micronized), Rosuvastatin calcium
8	Manufactured	Rovazet tab. 10/2.5mg	HK inno.N corporation	2023-02-10	Antiarterioscle-rotic agents	Rosuvastatin calcium, Ezetimibe
9	Manufactured	DAPAGREEN-G TAB. 10/4mg	JINYANG PHARM CO.,LTD.	2023-02-22	Antidiabetics	Dapagliflozin propanediol hydrate, Glimepiride
10	Manufactured	ESODUO-S Tab. 20/700mg	Chong Kun Dang Pharm.	2023-02-22	Peptic ulcer drugs	Esomeprazole magnesium trihydrate, Sodium bicarbonate
11	Manufactured	ESODUO-S Tab. 40/700mg	Chong Kun Dang Pharm.	2023-02-22	Peptic ulcer drugs	Esomeprazole magnesium trihydrate, Sodium bicarbonate
12	Manufactured	Gluxiga Tab. 10/4mg	HUTECS KOREA PHARMACEUTICAL CO.,LTD.	2023-02-28	Antidiabetics	Dapagliflozin propanediol hydrate, Glimepiride
13	Manufactured	Dapamepi Tab. 10/4mg	KyungDong Pharm. Co., Ltd.	2023-02-28	Antidiabetics	Dapagliflozin propanediol hydrate, Glimepiride
14	Manufactured	Xig double m tab. 10/4mg	MOTHER'S PHARMACEUTICAL.	2023-02-28	Antidiabetics	Dapagliflozin propanediol hydrate, Glimepiride
15	Manufactured	Daviduo Tab. 10/2.5mg	GC Biopharma Corp.	2023-03-07	Antiarterioscle-rotic agents	Ezetimibe (micronized), Rosuvastatin calcium

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
16	Manufactured	Rozeduo Tab. 10/2.5mg	Jeil Pharmaceutical co.,Ltd	2023-03-10	Antiarterioscle-rotic agents	Ezetimibe (micronized), Rosuvastatin calcium
17	Manufactured	Ezerosu Tab. 10/2.5mg	SHIN POONG PHARM. CO., LTD	2023-03-10	Antiarterioscle-rotic agents	Rosuvastatin calcium, Ezetimibe
18	Manufactured	Rosuemzet Tab. 10/2.5mg	MOTHER'S PHARMACEUTICAL.	2023-03-31	Antiarterioscle-rotic agents	Rosuvastatin calcium, Ezetimibe
19	Manufactured	Suprepmini Tab.	Taejoon Pharmaceutical Co., Ltd.	2023-04-19	X-ray contrast agent	Sodium sulfate anhydrous, magnesium sulfate anhydrous, potassium sulfate
20	Imported	Low Osmo Peri injection	Fresenius Kabi Korea Ltd.	2023-04-25	Protein amino acid preparations	L-Serine, L-Valine, L-Leucine, Glycine, Taurine, L-Alanine, L-Tyrosine, L-Proline, Potassium Chloride, L-Threonine, L-Arginine, L-Histidine, L-Methionine L-Isoleucine, L-Tryptophan, Soybean Oil, L-Phenylalanine, Purified Olive Oil, Glucose Monohydrate, L-Lysine Acetate, Zinc Sulfate Heptahydrate, Calcium Chloride Hydrate, Sodium Glycerophosphate, Triglycerides Medium-Chain, Magnesium Sulfate Heptahydrate, Sodium Acetate Hydrate, Purified Fish Oil (High Dose Omega-3 Fatty Acids)
21	Manufactured	Dapasita-M SR tab. 10/100/1000mg	Daewon Pharmaceutical Co., Ltd.	2023-05-22	Antidiabetics	Sitagliptin phosphate hydrate, dapagliflozin propanediol hydrate, metformin Hydrochloride with Colloidal Anhydrous Silica
22	Manufactured	Sildapa M SR Tab. 5/50/1000mg	Hanmi Pharm. Co.,Ltd.	2023-05-22	Antidiabetics	Sitagliptin phosphate hydrochloride, metformin hydrochloride, dapagliflozin propanediol hydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
23	Manufactured	Sildapa M SR Tab. 5/50/500mg	Hanmi Pharm. Co.,Ltd.	2023-05-22	Antidiabetics	Sitagliptin phosphate hydrochloride, metformin hydrochloride, dapagliflozin propanediol hydrate
24	Manufactured	Sildapa M SR Tab. 5/50/750mg	Hanmi Pharm. Co.,Ltd.	2023-05-22	Antidiabetics	Sitagliptin phosphate hydrochloride, metformin hydrochloride, dapagliflozin propanediol hydrate
25	Manufactured	Pevarozet Tab. 2/10 mg	Ahngook Pharm	2023-05-24	Antiarteriosclr-otic agents	Pitavastatin calcium, Ezetimibe
26	Manufactured	Pevarozet Tab. 4/10mg	Ahngook Pharm	2023-05-24	Antiarteriosclr-otic agents	Pitavastatin calcium, Ezetimibe
27	Manufactured	Hanwharocan Tab. 10/16mg	Han Wha Pharma Co., Ltd.	2023-05-24	Miscellaneous circulatory system drugs	Candesartan cilexetil, Rosuvastatin calcium
28	Manufactured	Hanwharocan Tab. 10/8mg	Han Wha Pharma Co., Ltd.	2023-05-24	Miscellaneous circulatory system drugs	Candesartan cilexetil, Rosuvastatin calcium
29	Manufactured	Hanwharocan Tab. 20/32mg	Han Wha Pharma Co., Ltd.	2023-05-24	Miscellaneous circulatory system drugs	Candesartan cilexetil, Rosuvastatin calcium
30	Manufactured	Hanwharocan Tab. 5/16mg	Han Wha Pharma Co., Ltd.	2023-05-24	Miscellaneous circulatory system drugs	Candesartan cilexetil, Rosuvastatin calcium
31	Manufactured	Hanwharocan Tab. 5/8mg	Han Wha Pharma Co., Ltd.	2023-05-24	Miscellaneous circulatory system drugs	Candesartan cilexetil, Rosuvastatin calcium
32	Manufactured	STAZET Tab. 2/10mg	Hanlim Pharm. Co., Ltd	2023-05-25	Antiarteriosclr-otic agents	Pitavastatin calcium, Ezetimibe
33	Manufactured	STAZET Tab. 4/10mg	Hanlim Pharm. Co., Ltd	2023-05-25	Antiarteriosclr-otic agents	Pitavastatin calcium, Ezetimibe
34	Manufactured	Lzerozet Tablet 2/10mg	Boryung Co., Ltd.	2023-05-25	Antiarteriosclr-otic agents	Pitavastatin calcium, Ezetimibe
35	Manufactured	Lzerozet Tablet 4/10mg	Boryung Co., Ltd.	2023-05-25	Antiarteriosclr-otic agents	Pitavastatin calcium, Ezetimibe
36	Manufactured	Tavalozet 2/10mg	Daewon Pharmaceutical Co., Ltd.	2023-05-25	Antiarteriosclr-otic agents	Pitavastatin calcium, Ezetimibe
37	Manufactured	Tavalozet 4/10mg	Daewon Pharmaceutical Co., Ltd.	2023-05-25	Antiarteriosclr-otic agents	Pitavastatin calcium, Ezetimibe
38	Manufactured	PZ Tab. 2/10mg	Dongkwang Pharm. Co., Ltd.	2023-05-25	Antiarteriosclr-otic agents	Pitavastatin calcium, Ezetimibe
39	Manufactured	PZ Tab. 4/10mg	Dongkwang Pharm. Co., Ltd.	2023-05-25	Antiarteriosclr-otic agents	Pitavastatin calcium, Ezetimibe

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
40	Manufactured	Atovamibe Tablet 10/5mg(Ezetimibe, Atorvastatin calcium trihydrate)	YUHAN Coporation	2023-05-26	Antiarterioscler-otic agents	Ezetimibe, atorvastatin calcium trihydrate
41	Manufactured	Adtamib Plus Tab 10/20/10mg	Addpharma, Inc.	2023-05-31	Miscellaneous circulatory system drugs	Ezetimibe (micronized), amlodipine besylate, atorvastatin calcium trihydrate
42	Manufactured	Adtamib Plus Tab 10/20/5mg	Addpharma, Inc.	2023-05-31	Miscellaneous circulatory system drugs	Ezetimibe (micronized), amlodipine besylate, atorvastatin calcium trihydrate
43	Manufactured	Adtamib Plus Tab 10/40/10mg	Addpharma, Inc.	2023-05-31	Miscellaneous circulatory system drugs	Ezetimibe (micronized), amlodipine besylate, atorvastatin calcium trihydrate
44	Manufactured	Rabepid Tablet 20/600mg	YUHAN Coporation	2023-06-08	Peptic ulcer drugs	Rabeprazole Sodium, Precipitated Calcium Carbonate
45	Manufactured	WINUF A PLUS Inj.	JW Life Science	2023-06-28	Protein amino acid preparations	L-Serine, L-Valine, L-Leucine, Glycine, L-Alanine, L-Tyrosine, L-Proline, Potassium Chloride, L-Threonine, L-Arginine, L-Histidine, L-Tryptophan, L-Methionine, L-Isoleucine, Refined Soyabean Oil|, L-Phenylalanine, L-Tryptophan, L-Lysine Hydrochloride, Purified Olive Oil, Glucose Monohydrate, Calcium Chloride Hydrate, Zinc Sulfate Heptahydrate, Triglycerides Medium-Chain, Magnesium Sulfate Heptahydrate, Sodium Acetate Hydrate, Sodium Glycerophosphate Hydrate, Purified Fish Oil (High Dose Omega-3 Fatty Acids)

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
46	Manufactured	Rostel plus tab. 40/5/10mg	Sam-chun-dang Pharm	2023-06-29	Miscellaneous circulatory system drugs	Rosuvastatin calcium (micronized), telmisartan, amlodipine besylate
47	Manufactured	Rostel plus tab. 80/5/10mg	Sam-chun-dang Pharm	2023-06-29	Miscellaneous circulatory system drugs	Rosuvastatin calcium (micronized), telmisartan, amlodipine besylate
48	Manufactured	BENAMET Tab. 0.3/1000mg	Daewoong Bio Inc.	2023-06-29	Antidiabetics	Metformin Hydrochloride, inovogliflozin
49	Manufactured	EAGLEDUO SR Tablet 0.3/1000mg (Enavogliflozin, Metformin Hydrochloride)	HANALL BIOPHARMA CO., LTD.	2023-06-29	Antidiabetics	Metformin Hydrochloride, Enavogliflozin
50	Manufactured	Sita-act tab. 100/15mg	Daewoo pharm	2023-07-28	Antidiabetics	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
51	Manufactured	Sita-act tab. 100/30mg	Daewoo pharm	2023-07-28	Antidiabetics	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
52	Manufactured	Sitapio 100/15mg Tab	Hyundai Pharm Co., Ltd.	2023-07-31	Miscellaneous circulatory system drugs	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
53	Manufactured	Sitapio 100/30mg Tab.	Hyundai Pharm Co., Ltd.	2023-07-31	Miscellaneous circulatory system drugs	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
54	Manufactured	JANUACTO Tab. 100/15mg	JINYANG PHARM CO.,LTD.	2023-07-31	Miscellaneous circulatory system drugs	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
55	Manufactured	JANUACTO Tab. 100/30mg	JINYANG PHARM CO.,LTD.	2023-07-31	Miscellaneous circulatory system drugs	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
56	Manufactured	Janupio Tab. 100/15mg	Daewon Pharmaceutical Co., Ltd.	2023-07-31	Miscellaneous circulatory system drugs	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
57	Manufactured	Janupio Tab. 100/30mg	Daewon Pharmaceutical Co., Ltd.	2023-07-31	Miscellaneous circulatory system drugs	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
58	Manufactured	Suvexx Tablet	SK Chemicals Co., Ltd.	2023-08-01	Antipyretic. analgesic. and antiinflammatory	Sumatriptan succinate, Naproxen sodium
59	Manufactured	Piosita Tab. 100/30mg	Samik Pharmaceutical Co., Ltd.	2023-08-07	Antidiabetics	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
60	Manufactured	Sitadion tab. 100/15mg	MOTHER'S PHARMACEUTICAL	2023-08-08	Antidiabetics	Sitagliptin phosphate hydrate, pioglitazone hydrochloride

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
61	Manufactured	Sitadion tab. 100/30mg	MOTHER'S PHARMACEUTICAL.	2023-08-08	Antidiabetics	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
62	Manufactured	Pioglsita Tab. 100/15mg	MEDICA KOREA Co., Ltd.	2023-08-08	Antidiabetics	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
63	Manufactured	Pioglsita Tab. 100/30mg	MEDICA KOREA Co., Ltd.	2023-08-08	Antidiabetics	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
64	Manufactured	Piovia Tab. 100/15mg	HUTECS KOREA PHARMACEUTICAL CO.,LTD.	2023-08-08	Antidiabetics	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
65	Manufactured	Piovia Tab. 100/30mg	HUTECS KOREA PHARMACEUTICAL CO.,LTD.	2023-08-08	Antidiabetics	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
66	Manufactured	Piosita Tab. 100/15mg	Samik Pharmaceutical Co., Ltd.	2023-08-08	Antidiabetics	Sitagliptin phosphate hydrate, pioglitazone hydrochloride
67	Manufactured	NailrockCombi Tab.	HUTECS KOREA PHARMACEUTICAL CO.,LTD.	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
68	Manufactured	Duojoin Tab.	PharmGen Science, Inc.	2023-08-10	Antipyretic. analgesic and anti-inflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
69	Manufactured	Laycelco tablet	Korea Arlico Pharm Co.,Ltd.	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
70	Manufactured	Lecox tab.	Samil Pharm. Co., Ltd.	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
71	Manufactured	Lexduo Tablet	HLB Pharmaceutical Co., Ltd.	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
72	Manufactured	BEARCOXIBPLUS TAB.	Daewoong Bio Inc.	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
73	Manufactured	BONE COX Tablet	UNIMED PHARM INC.	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
74	Manufactured	Celeduo Tab.	GENUONE Sciences Inc.	2023-08-10	Miscellaneous circulatory system drugs	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
75	Manufactured	CELLEBRON tab.	Dongkook Pharmaceutical Co.,Ltd.	2023-08-10	Miscellaneous circulatory system drugs	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
76	Manufactured	Celeina Tab.	IL HWA CO.,LTD.	2023-08-10	Antipyretic. analgesic and anti-inflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
77	Manufactured	Selecaduo Tab.	KyungDong Pharm. Co., Ltd.	2023-08-10	Antipyretic. analgesic and anti-inflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
78	Manufactured	Celetec tab.	Myungmoon Pharm. Co., Ltd.	2023-08-10	Miscellaneous circulatory system drugs	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
79	Manufactured	Cebkhan Plus Tab.	BASKHANBIO. PHARMA Inc.	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
80	Manufactured	C-cox-plus tab.	CMG Pharmaceutical Co., Ltd	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
81	Manufactured	ARIA DS Tab.	JINYANG PHARM CO.,LTD.	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
82	Manufactured	Asbon Plus Tab.	SAMJIN PHARM.CO.,LTD	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
83	Manufactured	Uniila plus tab.	Union Korea Pharm Co. LTD.	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
84	Manufactured	Coxduo tab.	Kwangdong Pharm Co., Ltd.	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
85	Manufactured	Cox2 Plus Tab.	Ahngook Pharm	2023-08-10	Antipyretic. analgesic and antiinflammatory	Celecoxib, Angelica Gigas Root·Chaenomelis Fructus·Saposhnikovia Root·Dipsaci Radix·Acanthopanax Root Bark·Achyranthes Root·Clematidis Radix·Cinnamon Bark·Gentianae Macrophyllae Radix·Cnidium Rhizome·Gastrodia Rhizome·Safflower 25% Ethanol Soft Extract (3.5→1)
86	Manufactured	Omest Soft Capsule 10/1000mg	Hanmi Pharm. Co.,Ltd.	2023-08-30	Antiarterioscle -rotic agents	Rosuvastatin calcium, Omega-3-Acid Ethyl Esters 90
87	Manufactured	Omest Soft Capsule 5/1000mg	Hanmi Pharm. Co.,Ltd.	2023-08-30	Antiarterioscle -rotic agents	Rosuvastatin calcium, Omega-3-Acid Ethyl Esters 90

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
88	Manufactured	WINUF A PLUS Peri inj.	JW Life Science	2023-08-31	Protein amino acid preparations	L-Serine, L-Valine, L-Leucine, Glycine, L-Alanine, L-Tyrosine, L-Proline, Potassium Chloride, L-Threonine, L-Arginine, L-Histidine, L-Tryptophan, L-Methionine, L-Isoleucine, Refined Soyabean Oil, Phenylalanine, L-Lysine Hydrochloride, Purified Olive Oil, Glucose Monohydrate, Calcium Chloride Hydrate, Zinc Sulfate Heptahydrate, Triglycerides Medium-Chain, Magnesium Sulfate Heptahydrate, Sodium Acetate Hydrate, Sodium Glycerophosphate Pentahydrate, Purified Fish Oil (High Dose Omega-3 Fatty Acids)
89	Manufactured	DUGLOW Tab. 10/15mg	Jeil Pharmaceutical co.,Ltd	2023-09-27	Antidiabetics	Dapagliflozin propanediol hydrate, Pioglitazone hydrochloride
90	Manufactured	Raspirin Cap. 100/5mg(Aspirin, Rabeprazole)	Hanmi Pharm. Co.,Ltd.	2023-10-30	Miscellaneous circulatory system drugs	Rabeprazole sodium, aspirin enteric pellets
91	Manufactured	Rapiduo Tab. 10/350mg	Daehan New Pharm Co.,Ltd	2023-12-18	Peptic ulcer drugs	Rabeprazole sodium, Magnesium oxide
92	Manufactured	Pioda Tab. 10/15mg (Dapagliflozin, pioglitazone)	YooYoung Pharmaceutical Co., Ltd	2023-12-29	Antidiabetics	Dapagliflozin propanediol hydrate, Pioglitazone hydrochloride

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

Table 37. Drugs Requiring Data Submission with Changes in Strength of Active Ingredients Approved in 2023

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Remark
1	Manufactured	Akarb tablet 30/40mg	Boryung Co., Ltd.	2023-02-28	Miscellaneous circulatory system drugs	High strength → Low strength
2	Manufactured	Akarb tablet 60/40mg				
3	Manufactured	K-CAB ODT 25mg	HK inno.N corporation	2023-02-28	Peptic ulcer drugs	High strength → Low strength
4	Manufactured	Exiaban Tab. 15mg	GENUONE Sciences Inc.	2023-03-24	Anticoagulant	High strength → Low strength
5	Manufactured	Exiaban Tab. 30mg				
6	Manufactured	Megaxaban tab. 15mg	Handok Inc.	2023-04-12	Anticoagulant	High strength → Low strength
7	Manufactured	Megaxaban tab. 30mg				
8	Manufactured	Enxiana Tab. 15mg	HUTECS KOREA PHARMACEUTICAL CO.,LTD.	2023-04-12	Anticoagulant	High strength → Low strength
9	Manufactured	Enxiana Tab. 30mg				
10	Manufactured	Genupharma Edoxaban Tab. 15mg	GENUPharma Inc.	2023-04-12	Anticoagulant	High strength → Low strength
11	Manufactured	Genupharma Edoxaban Tab. 30mg				
12	Manufactured	Closartan Tab. 50/6.25mg(Losartan Potassium/ chlorthalidone)	Hanmi Pharm. Co.,Ltd.	2023-04-28	Antihypertensives	Single agent → Compound agent
13	Imported	Fello OD Tab. 20mg	MYUNG IN PHARM.CO.,LTD.	2023-05-01	Miscellaneous circulatory system drugs	Low strength → High strength
14	Manufactured	Myungdopar Tab. 12.5/50mg	MYUNG IN PHARM.CO.,LTD.	2023-05-17	Central nervous system drugs	High strength → Low strength
15	Manufactured	Atova Tablet 5mg(Atorvastatin calcium trihydrate)	YUHAN Coporation	2023-05-18	Antiarteriosclerotic agents	High strength → Low strength
16	Imported	Aminomix Peripheral solution for infusion	Fresenius Kabi Korea Ltd.	2023-06-09	Protein amino acid preparations	High strength → Low strength

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Remark
17	Manufactured	Hypezil Tab. 3mg	Hyundai Pharm Co., Ltd.	2023-06-28	Central nervous system drugs	High strength → Low strength
18	Manufactured	Dapasita-M SR tab. 5/50/500mg	Daewon Pharmaceutical Co., Ltd.	2023-06-30	Antidiabetics	High strength → Low strength
19	Manufactured	Dapasita-M SR tab. 5/50/750mg				
20	Manufactured	Dapasita-M SR tab. 5/50/1000mg				
21	Imported	Nelclear Topical Solution (Terbinafine Hydrochloride)	KOLON PHARMA	2023-07-12	Antiparasitic dermatological agent	Low strength → High strength
22	Manufactured	ANYDIPINE S TAB 1.25MG	Chong Kun Dang Pharm.	2023-08-01	Antihypertensives	High strength → Low strength
23	Manufactured	Omapplusone Inj.	HK inno.N corporation	2023-09-07	Protein amino acid preparations	High strength → Low strength
24	Manufactured	Omapplusone Peri Inj.	HK inno.N corporation	2023-09-07	Protein amino acid preparations	High strength → Low strength
25	Manufactured	Telmiduoplus Tablet 40/5/5mg	Jeil Pharmaceutical co.,Ltd	2023-09-21	Miscellaneous circulatory system drugs	High strength → Low strength
26	Manufactured	Telmiduoplus Tablet 80/5/5mg	Jeil Pharmaceutical co.,Ltd	2023-09-21	Miscellaneous circulatory system drugs	High strength → Low strength
27	Manufactured	Neustatin-TS 40/5/5mg	SAMJIN PHARM.CO.,LTD	2023-09-25	Miscellaneous circulatory system drugs	High strength → Low strength
28	Manufactured	Neustatin TS Tab. 80/5/5mg	SAMJIN PHARM.CO.,LTD	2023-09-25	Miscellaneous circulatory system drugs	High strength → Low strength
29	Manufactured	Rostel plus tab. 40/5/5mg	Sam-chun-dang Pharm	2023-09-25	Miscellaneous circulatory system drugs	High strength → Low strength
30	Manufactured	Rostel plus tab. 80/5/5mg	Sam-chun-dang Pharm	2023-09-25	Miscellaneous circulatory system drugs	High strength → Low strength
31	Manufactured	Exone-R Tablet 5/160/2.5mg	HK inno.N corporation	2023-09-25	Miscellaneous circulatory system drugs	High strength → Low strength

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Remark
32	Manufactured	Exone-R Tablet 5/80/2.5mg	HK inno.N corporation	2023-09-25	Miscellaneous circulatory system drugs	High strength → Low strength
33	Manufactured	Telmionceplus Tab. 40/5/5mg	Myungmoon Pharm. Co., Ltd.	2023-09-25	Miscellaneous circulatory system drugs	High strength → Low strength
34	Manufactured	Telmionceplus Tab. 80/5/5mg	Myungmoon Pharm. Co., Ltd.	2023-09-25	Miscellaneous circulatory system drugs	High strength → Low strength
35	Manufactured	RABEMINI Tab.	Korea United Pharm.	2023-10-18	Peptic ulcer drugs	High strength → Low strength
36	Manufactured	RabepTop Tab. 10/400mg (Rabeprazole, Sodium bicarbonate)	Hanlim Pharm. Co., Ltd	2023-10-18	Peptic ulcer drugs	High strength → Low strength
37	Manufactured	RABEHALF Tab.	Korea biochem pharm	2023-10-18	Peptic ulcer drugs	High strength → Low strength
38	Manufactured	Sertarin Tab. 25mg	Hyundai Pharm Co., Ltd.	2023-10-25	Psychotropics	High strength → Low strength
39	Manufactured	ADDTAMIV PLUS TAB. 10/10/5mg (Ezetimibe, Atorvastatin Calcium Trihydrate, Amlodipine Besylate)	Addpharma Inc.	2023-10-25	Miscellaneous circulatory system drugs	High strength → Low strength
40	Manufactured	ADDTAMIV PLUS TAB. 10/10/10mg (Ezetimibe, Atorvastatin Calcium Trihydrate, Amlodipine Besylate)	Addpharma Inc.	2023-11-06	Miscellaneous circulatory system drugs	High strength → Low strength
41	Manufactured	Nebirosta Tab. 1.25/10mg	Elyson Pharmaceutical Co., Ltd	2023-11-09	Miscellaneous circulatory system drugs	High strength → Low strength

2.4.4. Drugs with New administration/ dosage

2 items of chemical drugs approved for new administration and dosage are imported and developed in new dosage forms to improve pediatric patient medication adherence (refer to Table 38).

Table 38. Drugs Requiring Data Submission with New administration/ dosage Approved in 2023

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Administration/Dose (partially omitted)
1	Imported	Slenyto 1mg prolonged-release tablets	Kuhnil Pharm. Co.,Ltd.	2023-11-15	Hypnotics sedatives	The recommended initial dose is 2 mg once daily. If an inadequate response is observed, increase to 5 mg, with a maximum daily dose of 10 mg. Administer orally once daily, 0.5 to 1 hour before bedtime, with or after a meal, and swallowing whole without chewing or crushing. This medication can be administered for up to 2 years and patients need to have their treatment response monitored regularly at least every 6 months.
2	Imported	Slenyto 5mg prolonged-release tablets	Kuhnil Pharm. Co.,Ltd.	2023-11-23	Hypnotics sedatives	

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr

2.4.5. Drugs with New Dosage Form (Same Route of Administration)

50 items of chemical drugs were approved for the new dosage form (same route of administration) (48 manufactured items and 2 imported items). Analyzing the types of development, the approved items are as follows: 26 items (23.3%) developed from capsules into tablets; 6 items developed from tablets to orally disintegrating tablets; 5 items (13.3%) developed from tablets to SR tablets; 4 items developed from SR capsule to SR tablets; 2 items developed from powder to liquid; 2 items developed from tablets or capsules to SR tablets; 1 item developed from tablet to powder for suspension, syrup or orally disintegrating film; 1 item developed from a vial to an ampoule; 1 item developed from ampoule to a prefilled syringe(refer to Table 39).

Table 39. Drugs Requiring Data Submission with New Dosage Form (Same Route of Administration) Approved in 2023

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	New Formulation
1	Manufactured	Easylax Sol.	INTRO BIO PHARMA	2023-01-04	Purgatives and clysters	Powder→ Liquid
2	Manufactured	Crirol Solution	KOREA PHARMA Co., Ltd.	2023-01-04	Purgatives and clysters	Powder→ Liquid
3	Manufactured	Light-Slim Tab. 60mg	Hana Pharm. Co., Ltd.	2023-01-06	Miscellaneous metabolic drugs	Capsule → Tablet
4	Manufactured	Olistat Tab. 60mg	Daehwa Pharmaceutical Co., Ltd.	2023-01-06	Miscellaneous metabolic drugs	Capsule → Tablet
5	Manufactured	Orlyone Tab. 60mg	CMG Pharmaceutical Co., Ltd	2023-01-06	Miscellaneous metabolic drugs	Capsule → Tablet
6	Manufactured	Zero-be Tab. 60mg	Daehan New Pharm Co.,Ltd	2023-01-06	Miscellaneous metabolic drugs	Capsule → Tablet
7	Manufactured	Zerowon Tablet 60mg (Orilstat)	WONKWANG PHARMA-CEUTICAL CORPORATION	2023-01-06	Miscellaneous metabolic drugs	Capsule → Tablet
8	Manufactured	Lumasate Prefilled Inj.	Hana Pharm. Co., Ltd.	2023-01-13	Antidote	Ampule → Pre-filled syringe
9	Manufactured	Gastric XR Tab.	Daehwa Pharmaceutical Co., Ltd.	2023-02-03	Peptic ulcer drugs	SR capsule → SR tablet
10	Manufactured	Gralise ER tablet 300 mg (Gabapentin)	Alvogen Korea Co., Ltd.	2023-03-20	Central nervous system drugs	Tablet, capsule → SR tablet
11	Manufactured	Gralise ER tablet 600 mg 9Gabapentin)	Alvogen Korea Co., Ltd.	2023-03-20	Central nervous system drugs	Tablet, capsule → SR tablet
12	Imported	XELJANZ oral solution 1mg/mL	Pfizer Pharmaceuticals Korea Limited	2023-03-20	Certified therapeutic agent (including non-specific immunosuppressants)	Tablet → Syrup
13	Manufactured	NEWPRAM OD Tab. 10mg	MYUNG IN PHARM.CO.,LTD.	2023-05-16	Psychotropics	Tablet → Orally disintegrating film
14	Manufactured	NEWPRAM OD Tab. 20mg	MYUNG IN PHARM.CO.,LTD.	2023-05-16	Psychotropics	Tablet → Orally disintegrating film
15	Manufactured	NEWPRAM OD Tab. 5mg	MYUNG IN PHARM.CO.,LTD.	2023-05-16	Psychotropics	Tablet → Orally disintegrating film
16	Manufactured	Jepram Melts OD Tablets 10mg	Jeil Pharmaceutical co.,Ltd	2023-05-17	Psychotropics	Tablet → Orally disintegrating film

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	New Formulation
17	Manufactured	Jepram Melts OD Tablets 20mg	Jeil Pharmaceutical co.,Ltd	2023-05-17	Psychotropics	Tablet → Orally disintegrating film
18	Manufactured	Jepram Melts OD Tablets 5mg	Jeil Pharmaceutical co.,Ltd	2023-05-17	Psychotropics	Tablet → Orally disintegrating film
19	Manufactured	Roxarex SR Tab. 75mg	PharmGen Science, Inc.	2023-05-24	Peptic ulcer drugs	SR capsule → SR tablet
20	Manufactured	Roxatirine XR Tab.	KOREA PRIME PHARM CO.,LTD	2023-05-24	Peptic ulcer drugs	SR capsule → SR tablet
21	Manufactured	Dong-A Pharm Diosmin Powder for Oral Suspension	Dong-A Pharmaceutical Co., Ltd.	2023-07-18	Vasoprotective agents	Tablet → Powder for suspension
22	Manufactured	Sleepfill ODF (Doxylamine succinate)	C.L.Pharm. Co., Ltd.	2023-07-24	Hypnotics sedatives	Tablet → Orally disintegrating film
23	Manufactured	Levoluka Tab.	GENUPharma Inc.	2023-08-23	Miscellaneous anti-allergic drugs	Capsule → Tablet
24	Manufactured	Levokas Tab.	DongKoo Bio&Pharma Co., Ltd.	2023-08-23	Miscellaneous anti-allergic drugs	Capsule → Tablet
25	Manufactured	Montebizal	Daewoong Pharmaceuticals	2023-08-23	Miscellaneous anti-allergic drugs	Capsule → Tablet
26	Manufactured	Lukalevo Tab.	Binex Co., Ltd.	2023-08-25	Miscellaneous anti-allergic drugs	Capsule → Tablet
27	Manufactured	Monteleple tab.	Daewon Pharmaceutical Co., Ltd.	2023-08-25	Miscellaneous anti-allergic drugs	Capsule → Tablet
28	Manufactured	Monteceti Tab.	MEDICA KOREA Co., Ltd.	2023-08-25	Miscellaneous anti-allergic drugs	Capsule → Tablet
29	Manufactured	Roxagen XR Tab.	SHIN POONG PHARM. CO., LTD	2023-08-28	Peptic ulcer drugs	SR capsule →SR tablet
30	Manufactured	Levomon Tab. (Montelukast Sodium, Levocetirizine Hydrochloride)	Huons Co., Ltd.	2023-08-30	Miscellaneous anti-allergic drugs	Capsule → Tablet
31	Manufactured	Levomong Tab	Daehwa Pharmaceutical Co., Ltd.	2023-08-30	Miscellaneous anti-allergic drugs	Capsule → Tablet
32	Manufactured	Monteduo Tablet	Boryung Co., Ltd.	2023-08-30	Miscellaneous anti-allergic drugs	Capsule → Tablet
33	Manufactured	Montekan plus Tab.	Jeil Pharmaceutical co.,Ltd	2023-08-31	Miscellaneous anti-allergic drugs	Capsule → Tablet

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	New Formulation
34	Manufactured	Monteragen tab 10/5mg (Montelukast, levocetirizine)	THERAGEN ETEX CO., LTD.	2023-09-12	Miscellaneous anti-allergic drugs	Capsule → Tablet
35	Manufactured	Montelol Plus Tab. 10/5mg	HLB Pharmaceutical Co., Ltd.	2023-09-12	Miscellaneous anti-allergic drugs	Capsule → Tablet
36	Manufactured	AlogliptinMet XR Tab. 12.5/1000mg	CELLTRION, INC.	2023-09-14	Antidiabetics	Tablet → SR Tablet
37	Manufactured	AlogliptinMet XR Tab. 12.5/500mg	CELLTRION, INC.	2023-09-14	Antidiabetics	Tablet → SR Tablet
38	Manufactured	AlogliptinMet XR Tab. 25/1000mg	CELLTRION, INC.	2023-09-14	Antidiabetics	Tablet → SR Tablet
39	Manufactured	Tralitin combi XR Tab. 5/1000mg	Daewon Pharmaceutical Co., Ltd.	2023-10-13	Antidiabetics	Tablet → SR Tablet
40	Manufactured	Traformin Duo SR Tab. 5/1000mg	Danagen	2023-10-16	Antidiabetics	Tablet → SR Tablet
41	Manufactured	Dongkook Dexmedetomidine HCl Injection(Ampoule)	Dongkook Pharmaceutical Co.,Ltd.	2023-10-30	Hypnotics sedatives	Vial → Ampule
42	Manufactured	Monkarizine Tab.	Hyundai Pharm Co., Ltd.	2023-10-30	Miscellaneous anti-allergic drugs	Capsule → Tablet
43	Manufactured	Montero Plus Tab.	Hana Pharm. Co., Ltd.	2023-10-30	Miscellaneous anti-allergic drugs	Capsule → Tablet
44	Manufactured	Monte Q Plus Tab. 10/5mg	Sam-chun-dang Pharm	2023-10-30	Miscellaneous anti-allergic drugs	Capsule → Tablet
45	Manufactured	Singulien Plus Tablet	Han Wha Pharma Co., Ltd.	2023-10-30	Miscellaneous anti-allergic drugs	Capsule → Tablet
46	Manufactured	Monteresin tablet (Montelukast sodium, Levocetirizine HCL)	COSMAX PHARMA CO., LTD.	2023-11-14	Miscellaneous anti-allergic drugs	Capsule → Tablet
47	Manufactured	Monteri M Tab.	MOTHER'S PHARMACEUTICAL.	2023-11-15	Miscellaneous anti-allergic drugs	Capsule → Tablet
48	Manufactured	Singulezine Tab.	HUTECS KOREA PHARMACEUTICAL CO.,LTD.	2023-11-15	Miscellaneous anti-allergic drugs	Capsule → Tablet
49	Manufactured	PASSRIZIN	Hanlim Pharm. Co., Ltd	2023-11-15	Miscellaneous anti-allergic drugs	Capsule → Tablet
50	Imported	Calquence tablet 100mg (Acalabrutinib maleate monohydrate)	AstraZeneca Korea	2023-12-28	Anti-tumor agents	Capsule → Tablet

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr

3

Approval Status of Biologics

3. Approval Status of Biologics

Analyzing the approval status of biologics (including advanced biological products) in 2023 by review type, there were 8 new drugs (excluding new drugs removed from the orphan drug list, etc.), 40 drugs requiring data submission (including 33 other drugs requiring data submission and drugs for export) and 13 orphan drugs (excluding 2 new orphan drugs) (refer to Table 40). When sorted by formulations, 22 biopharmaceuticals and 31 recombinant protein products were approved (refer to Table 41).

Table 40. Biologics Approved in 2023 by Review Type (Including Advanced Biological Products)

<Including Drugs for Export and Drug Substances>

No.	Review Type			Number of Approved Items
1	New drugs (8)	New drugs		6
2		Orphan drugs (15)	New orphan drugs	2
3	Drugs requiring data submission (51)		Orphan drugs (Biobetter)	13 (1)
4		Biosimilar products		12
5		Other drugs requiring data submission		26
Total				59

<Excluding Drugs for Export and Drug Substances>

No.	Review Type			Number of Approved Items
1	New drugs (8)	New Drugs		6
2		Orphan drugs (15)	New orphan drugs	2
3	Drugs requiring data submission (43)		Orphan drugs (Biobetter)	13 (1)
4		Biosimilar products		12
5		Other drugs requiring data submission		18
Total				51

Table 41. Biologics Approved in 2023 (Including Advanced Biological Products)

<Including Drugs for Export and Drug Substances>

Type	Total	Number of Approved Items		Remarks
		Manufac-tured	Imported	
Total	**59**	**20**	**39**	
Biopharmaceuticals	13	11	2	Drugs requiring data submission (13, including drugs for export (6), substance (1))
Recombinant Protein Products	45	9	36	New drugs (8), orphan drugs (12, excluding new orphan drug), drugs requiring data submission (25, including substance (1))
Advanced Biological Products	1	0	1	Orphan drug (1)

<Excluding Drugs for Export and Drug Substance>

Type	Total	Number of Approved Items		Remarks
		Manufac-tured	Imported	
Total	**51**	**12**	**39**	
Biopharmaceuticals	6	4	2	Drugs requiring data submission (6)
Recombinant Protein Products	44	8	36	New drugs (8), orphan drugs (12, excluding new orphan drugs), drugs requiring data submission (24)
Advanced Biological Products	1	0	1	Orphan drug (1)

3.1. Approval Status of Biopharmaceuticals

13 biopharmaceuticals were approved in 2023 (11 manufactured items, 2 imported items ; 6 vaccines, 6 antitoxin items, and 1 blood product), which was decreased by 9 items from the previous year (22 items) (refer to Table 42).

In particular, 6 vaccines were approved in 2023, which was decreased by 8 items from the previous year (14 items), which is interpreted as a result of the decrease in the number of COVID-19 vaccine approvals, which had increased in response to the surge of COVID-19 from 8 items in 2022 to 2 items in 2023.

Firstly, looking at the vaccine approval status, three vaccines were approved for domestic use: COVID-19 vaccine, pneumococcal vaccine, and influenza vaccine, while three vaccines were approved for export: COVID-19 vaccine, oral cholera vaccine, and varicella- zoster vaccine concentrated bulk solution. The efficacy and effectiveness of the vaccines authorized for domestic use are as follows.

"SPIKEVAX BIVALENT (Elasomeran, Davesomeran) (SARS-CoV-2 mRNA vaccine)" (Moderna Korea Ltd, approved on September 27, 2023) is a bivalent vaccine that expresses antigens from both the initial COVID-19 virus and the variant virus (Omicron, BA.4/5) and is intended for the prevention of COVID-19 caused by SARS-CoV-2 virus in persons 18 years of age and older.

"VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine [CRM197 Protein])" (MSD Korea Co., Ltd., approved on October 31,

2023) is a protein-conjugate polysaccharide vaccine for the prevention of invasive disease, pneumonia, and acute otitis media caused by streptococcus pneumonia, and is intended for the prevention of invasive disease and pneumonia caused by pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F).

“Efluelda PFS (Influenza Vaccine (Split Virion, Inactivated))” (SANOFI-AVENTIS KOREA Co., Ltd., approved on November 29, 2023) is an inactivated influenza split vaccine containing antigens from four virus strains (two influenza A and two influenza B strains), intended for the prevention of influenza disease caused by influenza A viruses and influenza B viruses in persons aged 65 years and older.

Next, 6 botulinum toxin preparations were approved, of which 2 were for domestic use, and their efficacy and effectiveness are as follows.

“INOBO 100 Unit (Clostridium botulinum Toxin Type A)” (INIBIO co., LTD., approved on July 19, 2023) is indicated for the temporary improvement of moderate to severe frown lines associated with the activity of the corrugator muscle and/or procerus muscle in adults aged 19 to 65 years.

“NEWLUX Inj. (Clostridium botulinum Toxin Type A)" (NUMECO, approved on August 30, 2023) is indicated for the temporary improvement of moderate to severe frown lines associated with corrugator muscle and/or procerus muscle activity in adults 19 to 65 years of age.

For blood products, 1 blood component is approved and its efficacy and effectiveness are as follows.

“Platelets, Pheresis, Leukocyte-depleted and Washed” (Korean Red Cross Daegu· Gyeongbuk Blood Center, approved on April 26, 2023) is a new blood component preparation manufactured using platelets, pheresis, leucocyte-deleted and is used to prevent or treat bleeding in patients with thrombocytopenia or platelet dysfunction.

Table 42. List of Approved Biopharmaceuticals in 2023

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/Effectiveness (partially summarized)	Remarks
1	Manufactured	SPIKEVAX BIVALENT (Elasomeran, Davesomeran) (SARS-CoV-2 mRNA vaccine))	SARS-CoV-2 Spike Protein encoded messenger Ribonucleic Acid(Elasomeran)(Host: DIG315, Vector: PL-022856) SARS-CoV-2 Spike Protein encoded messenger Ribonucleic Acid(Davesomeran)(Host: DIG315, Vector: PL-030872)	Moderna Korea Ltd.	2023-09-27	Prevention of COVID-19 caused by SARS-CoV-2 virus in persons 18 years and older	Drugs requiring data submission (Vaccine)
2	Imported	VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine [CRM197 Protein])	Purified Pneumococcal Polysaccharides (Serotype 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F) - Diphtheria Crm197 Protein Conjugate (Strain: S.Pneumoniae, Crm197 Strain: P.Fluorescens DC487, Crm197 Vector: p472-002)	MSD Korea Co., Ltd.	2023-10-31	Prevention of invasive disease and pneumonia, etc, caused by pneumococcal serotypes in infants, children, and adolescents, who are aged 6 weeks to 17 years	Drugs requiring data submission (Vaccine)
3	Imported	Efluelda PFS (Influenza Vaccine(Split Virion, Inactivated))	Purified Inactivated Influenza Virus Antigen B [B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type)], Purified Inactivated Influenza Virus Antigen B [B/Colorado/06/2017 - like strain (B/Maryland/15/2016, NYMC BX-69A)], urified Inactivated Influenza Virus Antigen A [A/Kansas/14/2017 like strain NYMCX-327(H3N2)][M269990]Purified Inactivated Influenza Virus Antigen A [A/Brisbane/02/2018(H1N1) pdm09 - like strain (A/Brisbane/02/2018, IVR-190)]	SANOFI-AVENTIS KOREA CO., LTD.	2023-11-29	Prevention of influenza illness in persons 65 years of age and older caused by influenza A and influenza B viruses in the vaccine	Drugs requiring data submission (Vaccine)
4	Manufactured	INIBO Inj. 100UNITS (Clostridium Botulinum Toxin Type A)	Clostridium Botulinum Type A	INIBIO Co., Ltd.	2023-07-19	Temporary improvement of moderate to severe frown lines associated with activity of the corrugator muscle and/or procerus muscle in adults 19 years of age and older but less than 65 years of age	Drugs requiring data submission (Anti-toxin)

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/Effectiveness (partially summarized)	Remarks
5	Manufactured	NEWLUX Inj. (Clostridium Botulinum Toxin Type A)	Clostridium Botulinum Toxin Type A (Strain: Hall)	NUMECO	2023-08-31	Temporary improvement of moderate to severe frown lines associated with activity of the corrugator muscle and/or procerus muscle in adults 19 years of age and older but less than 65 years of age	Drugs requiring data submission (Anti-toxin)
6	Manufactured	Platelets, Pheresis, Leukocyte-depleted and Washed	Washed platelets	Korean Red Cross Daegu Gyeongbuk Blood Center	2023-04-26	1. It is used to prevent or treat bleeding in patients with thrombocytopenia or platelet dysfunction. 2. It is indicated for patients with a history of plasma pro- tein -induced adverse transfusion reactions such as post-transfusion urticaria, allergic reactions, anaphylacticreactions, etc.	Drugs requiring data submission (Blood products)
7	Manufacrured	EuCorVac-19 Inj. Multi-dose(SARS-CoV-2 Spike Protein Vaccine (Recombinant))	EuCorVac-19 RBD Antigen	EUBIOLOGICS CO., LTD	2023-01-30	Prevention of COVID-19 caused by SARS-CoV -2 virus in persons 18 years and older	For export (Vaccine)
8	Manufactured	TYEMVERS for injection 200 units (Clostridium botulinum toxin type A) (For export)	Clostridium Botulinum Type A	CKD BiO Corp.	2023-02-09	Temporary improvement of moderate to severe frown lines asso- ciated with corruga- tor Muscle and/or procerus muscle activity in adults 19 years to 65 years	For export (Antitoxin)
9	Manufactured	TYEMVERS L for Injection (Clostridium botulinum Toxin Type A) (For Export)	Clostridium Botulinum Type A	CKD BiO Corp.	2023-03-24	Temporary improvement of moderate to severe frown lines associated with corrugator Muscle and/or procerus muscle activity in adults 19 years to 65 years	For export (Antitoxin)

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/Effectiveness (partially summarized)	Remarks
10	Manufactured	HITOX Injection 50Unit (Clostridium botulinum toxin type A)(for export)	Clostridium Botulinum Type A	BMI KOREA	2023-09-21	Temporary improvement of moderate to severe frown lines associated with corrugator Muscle and/or procerus muscle activity in adults 19 years to 65 years	For export (Antitoxin)
11	Manufactured	HITOX Injection 200Unit (Clostridium botulinum toxin type A)(for export)	Clostridium Botulinum Type A	BMI KOREA	2023-10-23	Temporary improvement of moderate to severe frown lines associated with corrugator muscle and/or procerus muscle activity in adults 19 years of age to 65 years of age	For export (Antitoxin)
12	Manufactured	BARYCELA Bulk	Live Attenuated Varicella Vaccin	GC Biopharma Corp.	2023-11-29	For manufacturing drug product	For export, drug substance (Vaccine)
13	Manufactured	Euvichol-S	Inactivated Cholera (Vibrio choleraeO1 Ogawa Cairo 50 Classical biotype, Formalininactivated, Vibrio choleraeO1 Inaba Phil 6973 El Tor biotype, Formalininactivated)	EuBiologics Co., Ltd.	2023-12-19	Prevention of cholera caused by Vibrio cholerae serogroup O1 in pediatrics 1 year of age and older, adolescents, and adults	For export (Vaccine)

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr

3.2. Approval Status of Recombinant Protein Products

1) Overview

A total of 45 recombinant protein products were newly approved in 2023 (9 manufactured items and 36 imported items), they are sorted on the basis of review type as follows: 8 new drugs (including new orphan drugs, 7 ingredients), showing a modest increase from 6 items (5 ingredients) in the previous year and 12 orphan drugs (10 ingredients; excluding 2 new orphan drugs, including 1 incrementally modified drug), indicating a significant increase from 6 items (5 ingredients) in the previous year. The increasing trend represents that the orphan drugs have been in the active development.

In addition, 25 drugs requiring data submission were approved and the major information on the approved new drugs and orphan drugs by item in 2023 are as follows (refer to Table 43).

“Vabysmo IVT (Faricimab)” (Roche Korea Co., Ltd., approved on January 20, 2023) is a bispecific antibody that selectively binds to and neutralizes both vascular endothelial growth factor-A (VEGF-A) and angiopoietin-2, thereby reducing vascular permeability and inflammation and inhibiting angiogenesis. It is approved for the treatment of neovascular (wet) age-related macular degeneration.

“Imjudo injection (Tremelimumab)” (AstraZeneca Korea, approved on June 23, 2023) is a new drug indicated in combination with durvalumab for the first-line treatment of adult patients with advanced or

unresectable hepatocellular carcinoma and designed to activate and proliferate T-cells by selectively blocking the interaction of cytotoxic T lymphocyte associated antigen-4 (CTLA-4) with CD80 and CD86, thereby increasing T-cell diversity and enhancing the antitumor immune response.

“Enjaymo injection (Sutimlimab)” (SANOFI-AVENTIS KOREA Co., Ltd., approved on July 12, 2023) is a new orphan drug used to treat hemolysis in adult patients with cold agglutinin disease, a type of autoimmune hemolytic anemia (AIHA) that causes hemolysis by agglutinating red blood cells at temperatures below normal body temperature, and inhibits hemolysis by interfering with the activation process of complement by binding to the complement protein C1s.

“Spevigo Injection (Spesolimab)” (Boehringer Ingelheim Korea, approved on August 9, 2023) is approved as a new orphan drug for the treatment of rapid exacerbations in adult patients with systemic pustular psoriasis. Spesolimab is a monoclonal antibody that binds to and antagonizes the human interleukin 36 receptor (IL-36R) and inhibits the subsequent activation of IL-36R, thereby reducing mediated inflammation and stopping the production of pathogenic cytokines.

“Adtralza 150 mg (Tralokonumab)” (LEO Pharma, approved on August 31, 2023) is a humanized monoclonal antibody that binds to interleukin-13 (IL-13) and inhibits interleukin receptor downstream signaling that causes inflammatory responses. It is approved for the treatment of atopic dermatitis.

“Tevimbra inj. 100mg (Tislelizumab)” (BeiGene Korea, approved on November 20, 2023) is a new drug used to treat esophageal squamous cell carcinoma. Tumor cells express PD-L1 on their surface to bind with PD-1 of immune cells (T cells) to evade attack by immune cells, and the drug interferes with the binding of PD-1 and PD-L1 to help immune cells eliminate cancer cells.

“Tezspire pre-filled syringe (Tezepelumab)”, “Tezspire autoinjector (Tezepelumab)” (AstraZeneca Korea, approved on December 21, 2023) is an anti-TSLP monoclonal antibody that targets and binds to thymis stromal lymphopoeitin (TSLP) which causes airway inflammation, and blocks TSLP and thereby reducing the secretion of a broad range of biomarkers and cytokines associated with inflammation. It is approved for the add-on maintenance treatment of severe asthma in patients 12 years of age and older who are inadequately controlled on existing therapy.

“PADCEV Injection 20 mg (enfortumab vedotin)”, “PADCEV Injection 30 mg (enfortumab vedotin)” (Astellas Pharma Korea Inc., approved on March 10, 2023) is an antibody-drug conjugate (ADC) that targets the nectin-4 protein which is highly expressed on the surface of urothelial carcinoma cells. It is an orphan drug used to treat advanced or metastatic urothelial carcinoma by binding to nectin-4 expressed on the cell surface and migrating into the cell, where it releases a drug (vedotin, monomethyl auristatin E (MMAE)) that inhibits cell division and induces carcinoma cell apoptosis.

“ObizurInj(Susoctocog alpha(Porcine coagulation factor VIII, Recombinant))” (Takeda Pharmaceuticals Korea Co., Ltd., approved on March 20, 2023) is an orphan drug approved for the treatment of bleeding in patients with acquired hemophilia A by temporarily replacing endogenous factor VIII for hemostasis.

“Trodelvy Injection (Sacituzumab govitecan)” (Gilead Sciences Korea Ltd., approved on May 9, 2023) is an antibody-drug conjugate (ADC) that targets the Trop-2 protein, which is highly expressed on the surface of breast cancer cells. It binds to Trop-2 expressed on the cell surface and migrates into the cell, releasing a drug (SN-38, SN-38 glucuronide) that inhibits cell division and induces cancer cell apoptosis, and is approved as an orphan drug for the treatment of advanced or metastatic triple-negative breast cancer.

“Minjuvi Inj. (Tafasitamab)” (Handok Inc., approved on June 9, 2023) is an orphan drug that binds to the B-cell surface antigen protein CD19 and directly induces cell death, antibody-dependent phagocytosis, and antibody-dependent cell-mediated cytotoxicity, resulting in B-cell depletion, and is indicated for the treatment of diffuse large B-cell lymphoma.

“Xenpozyme (Olipudase Alfa)” (SANOFI-AVENTIS KOREA CO., LTD., approved on July 25, 2023) is an orphan drug indicated for the long-term treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency, and is an enzyme replacement therapy that reduces sphingomyelin accumulation in organs by

supplying acid sphingomyelinase manufactured by genetic recombination technology.

“Tecvayli injection 30mg (Teclistamab)”, “Tecvayli injection 153mg (Teclistamab)” (Janssen Korea Ltd., approved on July 26, 2023) binds to BCMA, which is predominantly found on multiple myeloma cells, and to CD3 receptors expressed on the surface of T cells, activating T cells and inducing lysis and death of BCMA+ cells. It is an orphan drug for monotherapy in adult patients with relapsed or refractory multiple myeloma who have received three or more lines of therapy, including proteasome inhibitors, immunosuppressive agents, and anti-CD38 monoclonal antibodies.

“Lunsumio IV (Mosunetuzumab)” (Roche Korea Co., Ltd., approved on November 3, 2023) is an orphan drug indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more prior systemic therapies. It is an anti-CD20/CD3 bispecific antibody that targets CD20-expressing B cells, activates T cells by simultaneously binding to CD20 and CD3, and induces B cell lysis by releasing inflammatory cytokines from activated T cells.

“TAKHZYRO 300 mg solution for injection in pre-filled syringe (Lanadelumab)” (Takeda Pharmaceuticals Korea Co., Ltd., approved on November 24, 2023) is an orphan drug indicated for the routine prophylaxis of hereditary angioedema attacks, which are caused by a deficiency of the C1 esterase inhibitor factor resulting in recurrent angioedema without hives or pruritus. It prevents the release of

bradykinin from high molecular weight kininogen, thereby preventing the vascular leakage and edema that is initiated when bradykinin binds to the B2 receptor.

“Columvi IV (Glofitamab)” (Roche Korea Co., Ltd., approved on Decemember 7, 2023) is an orphan drug indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more prior systemic therapies. It is an anti-CD20/CD3 bispecific antibody that binds simultaneously to CD20 and CD3, activating and proliferating T cells and through secretion of cytokines and release of cytolytic proteins, inducing lysis of CD20-expressing B cells.

Table 43. List of Approved Recombinant Protein Products in 2023

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approved Date	Efficacy/Effectiveness (partially summarized)	Remarks
1	Imported	Vabysmo IVT (Faricimab)	Faricimab	Roche Korea Co., Ltd.	2023-01-20	Treatment of Neovascular (Wet) Age-Related Macular Degeneration Treatment of vision impairment caused by diabetic macular edema	New drug
2	Imported	Imjudo injection (Tremelimumab)	Tremelimumab	AstraZeneca Korea	2023-06-23	Combination therapy with durvalumab as first-line treatment for adult patients with advanced or unresectable HCC	New drug
3	Imported	Enjaymo injection (Sutimlimab)	Sutimlimab	SANOFI-AVENTIS KOREA Co., Ltd.	2023-07-12	Treating Hemolysis in Adult Patients with Cold Agglutinin Disease	New orphan drug
4	Imported	Spevigo Injedtion (Spesolimab)	Spesolimab	Boehringer Ingelheim Korea	2023-08-09	Treating rapid exacerbations in adult patients with systemic pustular psoriasis	New orphan drug
5	Imported	Adtralza 150 mg (Tralokinumab)	Tralokinumab	LEO Pharma	2023-08-31	Treatment of moderate to severe atopic dermatitis in adults 18 years of age and older and adolescents 12 to 17 years of age, who are candidates for systemic therapy that is not adequately controlled with topical therapies or for whom these therapies are not recommended	New drug
6	Imported	Tevimbra inj. 100mg (Tislelizumab)	Tislelizumab	BeiGene Korea	2023-11-20	Monotherapy in adult patients with unresectable, recurrent, locally advanced, or metastatic esophageal squamous cell carcinoma who are unable to continue prior platinum-based chemotherapy or who have relapsed or progressed since its administration	New drug
7	Imported	Tezspire pre-filled syringe (Tezepelumab)	Tezepelumab	AstraZeneca Korea	2023-12-21	Additional maintenance treatment for patients 12 years of age and older with severe asthma who are not adequately controlled on existing therapy.	New drug
8	Imported	Tezspire autoinjector (Tezepelumab)					New drug
9	Imported	PADCEV Injection	enfortumab	Astellas	2023-03-10	Treatment of adult patients	Orphan drug

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approved Date	Efficacy/Effectiveness (partially summarized)	Remarks
		20mg (Enfortumab vedotin)	vedotin	Pharma Korea Inc.		with locally advanced or metastatic urothelial cancer who have been previously treated with PD-1 or PD-L1 inhibitors and platinum- based chemotherapeutic agents	
10	Imported	PADCEV Injection 30mg (Enfortumab vedotin)					Orphan drug
11	Imported	ObizurInj [Susoctocog alpha(Porcine coagulation factor VIII, Recombinant)]	Susoctocog alpha	Takeda Pharmaceuticals Korea Co., Ltd.	2023-03-20	Treatment of bleeding in adult patients with acquired hemophilia A This medicine is not used to treat patients with von Willebrand disease.	Orphan drug
12	Imported	Nexviazyme injection (Avalglucosidase alfa)	Avalglucosidase alfa	SANOFI-AVENTIS KOREA Co., Ltd.	2023-03-29	It is used for long-term enzyme replacement therapy in patients diagnosed with Pompe disease (acid alpha-glucosidase deficiency).	Orphan drug (Biobetter)
13	Imported	Trodelvy Injection (Sacituzumab govitecan)	Sacituzumab govitecan	Gilead Sciences Korea Ltd.	2023-05-09	Treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of which was for metastatic disease.	Orphan drug
14	Imported	Minjuvi Inj. (Tafasitamab)	Tafasitamab	Handok Inc.	2023-06-09	In combination with lenalidomide, followed by monotherapy with this drug, in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not candidates for autologous stem cell transplantation (ASCT) and have failed one or more prior therapies	Orphan drug
15	Imported	Xenpozyme (Olipudase Alfa)	Olipudase Alfa	SANOFI-AVENTIS KOREA Co., Ltd.	2023-07-25	Enzyme Replacement Therapy for the Treatment of Non-CNS Manifestations of Acid Sphingomyelinase Deficiency (ASMD) in Pediatric and Adult Patients	Orphan drug
16	Imported	Tecvayli injection 30mg (Teclistamab)	Teclistamab	Janssen Korea Ltd.	2023-07-26	Monotherapy for adult patients with relapsed or refractory multiple myeloma who have received 3 or more prior lines of therapy, including proteasome inhibitors, immunosuppressive agents, and anti-CD38	Orphan drug
17	Imported	Tecvayli injection 153mg (Teclistamab)					Orphan drug

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approved Date	Efficacy/Effectiveness (partially summarized)	Remarks
						monoclonal antibodies	
18	Imported	Lunsumio IV (Mosunetuzumab)	Mosunetuzumab	Roche Korea Co., Ltd.	2023-11-03	Treatment of adult patients with relapsed or refractory vesicular lymphoma after two or more systemic therapies	Orphan drug
19	Imported	TAKHZYRO 300 mg solution for injection in pre-filled syringe (Lanadelumab)	Lanadelumab	Takeda Pharmaceuticals Korea Co., Ltd.	2023-11-24	Prevention of hereditary angioedema attacks in adults and adolescents 12 years of age and older	Orphan drug
20	Imported	Columvi IV (Glofitamab)	Glofitamab	Roche Korea Co., Ltd.	2023-12-07	Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more systemic therapies	Orphan drug
21	Imported	Adalloce 40 mg/0.4 mL solution for injection in pre-filled pen (Adalimumab, recombinant)	Adalimumab	SAMSUNG BIOEPIS Co., Ltd.	2023-01-03	(Adults) Rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis, Crohn's disease, psoriasis, ulcerative colitis, Behçet's enteritis, hidradenitis suppurativa, uveitis (Pediatric) Crohn's disease, idiopathic arthritis, plaque psoriasis	Drugs requiring data submission (Biosimilar)
22	Imported	Adalloce 40 mg/0.4 mL solution for injection in pre-filled syringe (Adalimumab, recombinant)					Drugs requiring data submission (Biosimilar)
23	Manufactured	Chong Kun Dang Ranibizumab PFS	Ranibizumab	Chong Kun Dang Pharm.	2023-05-19	Treatment of neovascular (wet) age-related macular degeneration, etc.	Drugs requiring data submission (Biosimilar)
24	Imported	Tuzepta Injection 150 mg (Trastuzumab)	Trastuzumab	SAMOH PHARM Co., Ltd.	2023-07-10	Metastatic Breast Cancer, Early Breast Cancer Metastatic Stomach Cancer	Drugs requiring data submission (Biosimilar)
25	Imported	Tuzepta Injection 440 mg (Trastuzumab)					Drugs requiring data submission (Biosimilar)
26	Manufactured	Panpotin Prefilled Syringe 6000 IU (Epoetin alfa)	Epoetin alfa	PanGen Biotech Inc.	2023-08-25	The following anemias are seen in patients with chronic renal failure 1) Symptomatic anemia 2) Anemia requiring transfusion	Drugs requiring data submission (Biosimilar)
27	Manufactured						Drugs

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approved Date	Efficacy/Effectiveness (partially summarized)	Remarks
		Panpotin Prefilled Syringe 10000 IU (Epoetin alfa)					requiring data submission (Biosimilar)
28	Imported	SciXimab Injection (Rituximab) (Monoclonal antibodies, recombinant)	Rituximab	SciGen Korea	2023-10-27	Lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, Wegener's sarcoidosis and microscopic polyangiitis	Drugs requiring data submission (Biosimilar)
29	Manufactured	XELENKA prefilled syringe Inj. 20mg/0.2mL (Adalimumab, recombinant)	Adalimumab	LG Chem Ltd.	2023-12-14	(Adults) Rheumatoid arthritis, psoriatic arthritis, ankylosing spondyloarthritis, Crohn's disease, psoriasis, ulcerative colitis, Behçet's enteritis, hidradenitis suppurativa, uveitis (Pediatric) Crohn's disease, idiopathic arthritis, plaque psoriasis	Drugs requiring data submission (Biosimilar)
30	Manufactured	Xelenka Autoinjector Inj. 40mg/0.4mL (Adalimumab, recombinant)					Drugs requiring data submission (Biosimilar)
31	Manufactured	XELENKA prefilled syringe Inj. 40mg/0.4mL (Adalimumab, recombinant)					Drugs requiring data submission (Biosimilar)
32	Manufactured	XELENKA prefilled syringe Inj. 80mg/0.8mL (Adalimumab, recombinant)				(Adults) Rheumatoid arthritis, Crohn's disease, Ulcerative colitis, Behcet's enteritis, Hidradenitis suppurativa, Uveitis (Pediatric) Crohn's disease	Drugs requiring data submission (Biosimilar)
33	Improted	Ngenla Prefilled Pen Injection 24mg (Somatrogon)	Somatrogon	Pfizer Pharmaceuticals Korea Limited	2023-01-31	Growth failure in children 3 years of age and older due to impaired pituitary growth hormone secretion	Drugs requiring data submission
34	Improted	Ngenla Prefilled Pen Injection 60 mg (Somatrogon)					Drugs requiring data submission
35	Improted	Praluent Pen Injection 300mg (Alirocumab)	Alirocumab	SANOFI-AVENTIS KOREA Co., Ltd.	2023-02-13	Primary hypercholesterolemia and mixed dyslipidemia, atherosclerotic cardiovascular disease	Drugs requiring data submission
36	Improted	Enbrel Dose-Dispenser Cartridge 50mg (Etanercept)	Etanercept	Pfizer Pharmaceuticals Korea Limited	2023-03-06	(Adults) Rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis, psoriasis (pediatric) idiopathic arthritis	Drugs requiring data submission
37	Improted	Wegovy Pre-filled	Semaglutide	Novo Nordisk	2023-04-27	As an adjunct to a	Drugs

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approved Date	Efficacy/Effectiveness (partially summarized)	Remarks
		Pen 1.7 (Semaglutide)				calorie-reduced diet and increased physical activity for weight management, including weight loss and weight maintenance, in adult patients who are - Obese patients with an initial body mass index (BMI) of 30 kg/m^2 or greater; or - Overweight patients with an initial body mass index (BMI) greater than or equal to 27 kg/m2 and less than or equal to 30 kg/m^2 who have one or more weight-related comorbidities [e.g., dysglycemia (pre-diabetes or type 2 diabetes), hypertension, dyslipidemia, obstructive sleep apnea, or cardio-vascular disease]	requiring data submission
38	Improted	Wegovy Pre-filled Pen 1.0 (Semaglutide)		Pharma Korea, Ltd.			Drugs requiring data submission
39	Improted	Wegovy Pre-filled Pen 0.25 (Semaglutide)					Drugs requiring data submission
40	Improted	Wegovy Pre-filled Pen 2.4 (Semaglutide)					Drugs requiring data submission
41	Improted	Wegovy Pre-filled Pen 0.5 (Semaglutide)					Drugs requiring data submission
42	Improted	Skyrizi Catridge Inj. (Risankizumab, recombinant)	Risankizumab	AbbVie Korea Ltd.	2023-11-15	Treatment of Adult patients 18 years and older with moderate to severe active Crohn's disease who have not responded adequately to, become unresponsive to, or are intolerant of conventional therapies or biologics	Drugs requiring data submission
43	Improted	Skyrizi Inj. (Risankizumab, recombinant)					Drugs requiring data submission
44	Manufactured	Growtropin-II injection (solution) i pen (Somatropin)	Somatropin	Dong-A ST	2023-11-24	Growth failure in children due to pituitary growth hormone secretion disorders, etc	Drugs requiring data submission
45	Manufactured	Dong-A Recombinant somatropin concentrated bulk solution II (Drug substance)	Somatropin	Dong-A ST	2023-10-31	For dispensing and manufac-turing drugs	Drugs requiring data submission (Drug substance)

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr

2) Approval Status of Biosimilar Products

Biosimilars are drugs with proven quality and non-clinical/clinical comparative equivalence to items already approved for manufacture, marketing, and import. From the initial domestic approval in 2021 to 2023, a total of 54 products with 28 ingredients were approved, of which 17 products with 39 ingredients were authorized for domestically developed equivalent biologics (refer to Table 44).

In 2023, 12 biosimilars (5 ingredients) were approved, 5 items more than 7 items (3 ingredients) in the previous year. By therapeutic class, 7 (58.3%) drugs for the treatment and diagnosis of tissue cells, 3 (25.0%) anti-tumor agents, and 4 (16.7%) hormonal medications were approved. Details of biosimilars approved in 2023 are as follows.

“Adalloce 40 mg/0.4 mL solution for injection in pre-filled syringe (Adalimumab, recombinant)”, “Adalloce 40 mg/0.4 mL solution for injection in pre-filled pen (Adalimumab, recombinant)” (SAMSUNG BIOEPIS Co., Ltd., approved on January 3, 2023) and **“XELENKA prefilled syringe Inj. 40mg/0.4mL (Adlimumamb, recombinant)”, “XELENKA prefilled syringe Inj. 20mg/0.2mL (Adlimumamb, recombinant)”, “Xelenka Autoinjector Inj. 40mg/0.4mL (Adalimumab, recombinant)”, “Xelenka Autoinjector Inj. 80mg/0.8mL (Adalimumab, recombinant)”** (LG Chem Ltd., approved on December 14, 2023) is a biosimilar developed domestically with a control drug of Humira (adalimumab) of AbbVie, Korea.

“Chong Kun Dang Ranibizumab PFS” (Chong Kun Dang Pharm. approved on May 19 2023) is a biosimilar developed in Korea with a control drug of Novartis Korea’s Lucentis 10 milligrams/milliliter

(ranibizumab, recombinant).

“Tuzepta Injection 150 mg (Trastuzumab)”, “Tuzepta Injection 440 mg(Trastuzumab)” (SAMOH PHARM Co., Ltd., approved on July 10, 2023) are biosimilars developed with a control drug of Roche Korea Co., Ltd.'s Herceptin (trastuzumab).

“Panpotin Prefilled Syringe 10000 IU (Epoetin alfa)”, “Panpotin Prefilled Syringe 6000 IU (Epoetin alfa)” (PanGen Biotech Inc., approved on August 25, 2023) is a biosimilar developed in Korea with a control drug of Jassen Korea's Eprex Prefilled Syringe (recombinant erythropoietin).

“SciXimab Injection (Rituximab) (monoclonal antibodies, recombinant)” (SciGen Korea, approved on October 27, 2023) is a biosimilar developed with a control drug of Mabthera injection (rituximab) of Roche Korea Co., Ltd. (monoclonal antibodies, recombinant).

Table 44. List of Approved Biosimilar Products (2012~2023)

No.	Product name	Company	Reference drug (Ingredient)	Efficacy/Effectiveness (partially summarized)	Approval date	Manufac-tured/ Imported
1	Remsima Inj. 100mg	Celltrion Pharm, Inc.	Remicade (Infliximap)	Rheumatoid arthritis, psoriasis, etc.	2012-07-20	Manufactured
2	Herzuma Inj. 150mg	Celltrion Pharm, Inc.	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2014-01-15	Manufactured
3	Herzuma Inj. 440mg					Manufactured
4	SciTropin A 5mg	SciGen Korea Co.,Ltd	Genotropin (Somatropin)	Growth failure of children, etc.	2014-01-28	Imported
5	SciTropin A 10mg					Imported
6	Davictrel Inj. 25mg	Hanwha Chemical Co.	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2014-11-11 (Withdrawn on 2015-09-30)	Manufactured

No.	Product name	Company	Reference drug (Ingredient)	Efficacy/Effectiveness (partially summarized)	Approval date	Manufac-tured/ Imported
7	Brenzys 50 mg Prefilled Syringe → (name changed to) Etoloce 50 mg solution for injection in pre-filled syringe	SAMSUNG BIOEPIS Co., Ltd.	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2015-09-07	Imported (developed in Korea)
8	Basaglar Cartridge 100unit/mL(Insulin Glargine, Recombinant)	Lilly Korea	Lantus (Insulin glargine)	Diabetes	2015-11-25 (Withdrawn on 2019-09-26)	Imported
9	Basaglar Kwikpen 100Unit/mL(Insulin Glargine, Recombinant)				2015-11-25	Imported
10	Renflexis Inj. 100 mg → (name change) Remaloce 100 mg powder for concentrate for solution for infusion	SAMSUNG BIOEPIS Co., Ltd.	Remicade (Infliximap)	Rheumatoid arthritis, ulcerative colitis, etc.	2015-12-04	Imported (developed in Korea
11	Truxima Inj.	Celltrion Pharm, Inc.	MabThera Inj. (Rituximab)	Rheumatoid arthritis, lymphoma, etc.	2015-07-16 2016-11-16 (Switched for domestic use)	Manufactured
12	Hadlima Prefilled Syringe 40 mg → (name changed to) Adalloce 40 mg solution for injection in pre-filled syringe	SAMSUNG BIOEPIS Co., Ltd.	Humira Inj. 40 mg (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis, etc.	2017-09-20	Imported (developed in Korea
13	Samfenet 150 mg powder for concentrate for solution for infusion	SAMSUNG BIOEPIS Co., Ltd.	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2017-11-08	Imported (developed in Korea
14	Glarzia Prefilled Pen	GC Pharma	Lantus (Insulin glargine)	Diabetes	2018-03-07	Imported
15	Glarzia Prefilled Pen	LG Chem Co., Ltd.	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2018-03-16	Manufactured
16	Eucept Prefilled Syringe Inj.					Manufactured
17	NESBELL 20	Chong Kun Dang pharm.	Nesp (Darbepoetin alpha)	Anemia in patients with chronic renal failure, etc.	2018-11-29	Manufactured
18	NESBELL 30					Manufactured
19	NESBELL 40					Manufactured
20	NESBELL 60					Manufactured
21	NESBELL 120					Manufactured
22	Etoloce 50 mg solution for injection in pre-filled pen	SAMSUNG BIOEPIS Co., Ltd.	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2019-08-19	Imported (developed in Korea
23	Terrosa Cartridge Inj.	Daewon Pharm. Co., Ltd	Forsteo (Teriparatide)	Osteoporosis	2019-10-29	Imported
24	Panpotin Prefilled Syringe 2000IU	PanGen Biotech Inc.	Eprex (Recombinant human erythropoietin)	Anemia in patients with chronic renal failure	2019-11-28	Manufactured
25	Panpotin Prefilled Syringe 4000IU					Manufactured
26	Adalloce 40 mg solution for injection in pre-filled pen	SAMSUNG BIOEPIS Co., Ltd.	Humira Inj. 40 mg (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis, etc.	2020-07-03	Imported (developed in Korea

No.	Product name	Company	Reference drug (Ingredient)	Efficacy/Effectiveness (partially summarized)	Approval date	Manufac-tured/ Imported
27	Ogivri Injection 150mg	Alvogen Korea Co., Ltd.	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2020-08-26	Imported
28	Samfenet 440 mg powder for concentrate for solution for infusion	SAMSUNG BIOEPIS Co., Ltd.	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2020-10-14	Imported (developed in Korea
29	Bemfola prefilled pen.(follitropin alfa)	YooYoung Pharmaceutical Co., Ltd.	Gonal-F Pen Inj. (Follitropin-alfa)	Ovarian hyperstimulation, anovulation	2020-10-29	Imported
30	Onbevzi inj.	SAMSUNG BIOEPIS Co., Ltd.	Avastin (Bevacizumab)	Metastatic colorectal cancer, etc.	2021-03-11	Imported (developed in Korea
31	Zyrabev	Pfizer Korea Ltd.	Avastin (Bevacizumab)	Metastatic colorectal cancer, etc.	2021-05-17	Imported
32	SciTropin A 15mg	SciGen Korea Co., Ltd	Genotropin (Somatropin)	Growth failure in children, etc.	2021-07-09	Imported
33	Yuflyma PFS 40mg/0.4mL	Celltrion Pharm, Inc.	Humira 40mg/0.4mL (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis, etc.	2021-10-15	Imported (developed in Korea
34	Yuflyma 40mg/0.4mL					Imported (developed in Korea
35	Bonsity pen injection	Pharmbio Korea Inc.	Forsteo (Teriparatide)	Osteoporosis	2021-11-16	Imported
36	Alymsys Injection	Alvogen Korea	Avastin (Bevacizumab)	Metastatic colorectal cancer, etc.	2022-01-19	Imported
37	AMELIVU 10mg/mL	SAMSUNG BIOEPIS Co., Ltd.	Lucentis Inj. (Ranibizumab)	Age-related macular degeneration, etc.	2022-05-13	Imported (Developed in Korea)
38	Yuflyma Pen Inj. 80mg/0.8mL	Celltrion	Humira 80mg/0.8mL (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis etc.	2022-06-15	Manufactured
39	Yuflyma PFS 80mg/0.8mL					Manufactured
40	Vegzelma	Celltrion	Avastin (Bevacizumab)	Metastatic colorectal cancer, etc.	2022-09-28	Manufactured
41	Chong Kun Dang Ranibizumab Inj. PFS	Chong Kun Dang Pharm.	Lucentis Injection (Ranibizumab)	Age-related macular degeneration, etc.	2022-10-20	Manufactured
42	Celltrion Yuflyma Pen Injection 40mg/0.4mL	CELLTRION, INC.	Humira 40mg/0.4mL (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis, etc.	2022-11-10	Manufactured
43	Adalloce 40 mg/0.4 mL solution for injection in pre-filled pen	SAMSUNG BIOEPIS Co., Ltd.	Humira Pen Injection 40mg/0.4mL (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis, etc.	2023-01-03	Imported (Developed in Korea)
44	Adalloce 40 mg/0.4 mL solution for injection in pre-filled syringe		Humira Pre-filled Syringe Injection 40mg/0.4mL (Adalimumab)			Imported (Developed in Korea)
45	Chong Kun Dang Ranibizumab PFS	Chong Kun Dang Pharm.	Lucentis Injection (Ranibizumab)	Age-related macular degeneration, etc.	2023-05-19	Manufactured

No.	Product name	Company	Reference drug (Ingredient)	Efficacy/Effectiveness (partially summarized)	Approval date	Manufac-tured/ Imported
46	Tuzepta Injection 150 mg	SAMOH PHARM Co., Ltd.	Herceptin® Inj. (Trastuzumab)	Breast cancer, gastric cancer	2023-07-10	Imported
47	Tuzepta Injection 440 mg		Herceptin® Inj. (Trastuzumab)			Imported
48	Panpotin Prefilled Syringe Injection 60000IU	PanGen Biotech Inc.	Eprex (Recombinant erythropoietin)	Anemia in patients with chronic renal failure	2023-08-25	Manufactured
49	Panpotin Prefilled Syringe Injection 10000IU					Manufactured
50	SciXimab Injection	SciGen Korea	Mabthera Injection (Rituximab)	Lymphoma, etc.	2023-10-27	Imported
51	XELENKA prefilled syringe Inj. 20mg/0.2mL	LG Chem Ltd.	Humira Injection 40mg (Adalimumab)	Rheumatoid arthritis, etc.	2023-12-14	Manufactured
52	Xelenka Auto injector Inj. 40mg/0.4mL					Manufactured
53	XELENKA prefilled syringe Inj. 40mg/0.4mL					Manufactured
54	XELENKA prefilled syringe Inj. 80mg/0.8mL					Manufactured

* Detailed approval information (efficacy/effectiveness, usage/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr.

3) Approval Status of Biobetter Products

Biobetters are drugs that are recognized by the Minister of Food and Drug Safety as having improved safety, efficacy, or effectiveness (compliance, convenience, etc.) compared to already approved biologics, or as being advanced in medical technology.

Since the approval of the first Biobetter product in Korea in 2015, a total of four items have been approved as Biobetter products(refer to Table 45), and one item was approved in 2023, and the efficacy and effectiveness are as follows.

"Nexviazyme injection (Avalglucosidase alfa)" (SANOFI-AVENTIS KOREA CO., LTD., approved March 29, 2023) has undergone pharmaceutical improvement compared to the approved Myozyme injection to enable dose escalation in patients who are refractory to the conventional dose. It is approved as an orphan drug for long-term enzyme replacement therapy in patients diagnosed with Pompe disease (acid alpha-glucosidase deficiency).

Table 45. List of Improved Biobetter Products (2015~2023)

No.	Manufactured /Imported	Product Name	Company	Ingredient	Approval Date	Efficacy /Effectiveness (partially summarized)	Remarks
1	Imported	Toujeo injection solostar	SANOFI-AVENTIS KOREA CO., LTD.	Insulin glargin	2015-08-13	Diabetes	
2	Imported	Phesgo® 1200/600mg	Roche Korea Co., Ltd.	Pertuzumab/ Trastuzumab	2021-09-06	Breast cancer	
3	Imported	Phesgo® 600/600mg					
4	Imported	Nexviazyme injection	SANOFI-AVENTIS KOREA CO., LTD.	Avalglucosidase alfa	2023-03-29	Long-term enzyme replacement therapy in patients diagnosed with Pompe disease (acid alpha-glucosida-se deficiency)	Orphan drug

3.3. Approval Status of Advanced Biological Products

1) Approval Status of Cell Therapy Products

With the enactment of the Act on the Safety and Support for Advanced Regenerative Medicine and Advanced Biological Products (hereinafter referred as the Advanced Regenerative Bio Act) in August 2020, established a regulatory framework for safety management of advanced biological products such as cell therapy and gene therapy drugs, that is distinct from the Pharmaceutical Affairs Act. The cell therapy products were reapproved in 2021 according to the the Advanced Regenerative Bio Act and a total of 13 items were approved as of 2023 (refer to Table 46).

Table 46. List of Approved Cell Therapy Products (2001~2023)

No.	Manufactured /Imported	Product Name	Ingredient	Company	Initial Approval Date	Re-Approval Date	Efficacy/Effectiveness (partially summarized)	Remarks
1	Manufactured	Holoderm	Autologous keratinocyte	Tego Science, Inc	2002-12-10	2021-08-27	1. The burn where second degree burn takes up not less than 30% of the body surface area 2. The burn where third degree burn takes up not less than 10% of the body surface	
2	Manufactured	Kaloderm	Allogeneic keratinocyte	Tego Science, Inc.	2005-03-21	2021-08-27	1. Promoting reepithelization of deep second degree burn 2. Promoting wound healing of diabetic foot ulcer that has good blood supply and is not founded to be infected	

No.	Manufactured /Imported	Product Name	Ingredient	Company	Initial Approval Date	Re-Approval Date	Efficacy/Effectiveness (partially summarized)	Remarks
3	Manufactured	Keraheal	Basol autologous keratinocyte	Biosolution Co., Ltd.	2006-05-03	2021-08-25	1. The burn where second degree burn takes up not less than 30% of the body surface area 2. The burn where third degree burn takes up not less than 10% of the body surface	
4	Manufactured	Immunecell LC Injection	LC autologous blood origin T lymphocyte	GC Cell	2007-08-06	2021-08-27	Adjuvant therapy for patients whose tumor has been removed after curative resection for hepatocellular carcinoma (operation, radio frequency ablation, percutaneous ethanol injection therapy)	
5	Manufactured	Queencell	Minimally anipulated autologous adipose tissue-derived fat cell	Anterogen Co., Ltd.	2010-03-26	2021-06-09	Improvement of subcutaneous fat defect	
6	Manufactured	CureSkin Inj.	Autologous dermal fibroblast	S.Biomedics Co., Ltd.	2010-05-11	2021-07-29	Improvement of dented scar area came from the acne treatment process	
7	Manufactured	Hearticellgram-AMI	Autologous bone marrow-derived mesenchymal stem cell	Pharmicell Co., Ltd.	2011-07-01	2021-08-26	Improvement of left ventricular ejection fraction in patients who had reperfused acute myocardial infarction by coronary angioplasty within 72 hours after chest pain	
8	Manufactured	Cartistem	Allogenic umbilical cord blood-derived mesenchymal stem cell	MEDIPOST Co., Ltd.	2012-01-18	2021-08-19	Treatment of knee cartilage defects in patients with degenerative or repetitive traumatic osteoarthritis(ICRS grade IV)	
9	Manufactured	Cupistem	Autologous adipose-derived mesenchymal stem cell	Anterogen Co., Ltd.	2012-01-18	2021-08-24	Treatment of fistula caused by Crohn's disease	Orphan drug
10	Manufactured	Neuronata® inj.	Autologous bone marrow-derived mesenchymal stem cell	Corestem Inc.	2014-07-30	2021-08-27	Alleviation of the disease progression rate of amyotrophic lateral sclerosis in combination with riluzole	Orphan drug

No.	Manufactured /Imported	Product Name	Ingredient	Company	Initial Approval Date	Re-Approval Date	Efficacy/Effectiveness (partially summarized)	Remarks
11	Manufactured	Keraheal-Allo	Basol allogeneic keratinocyte	Biosolution Co., Ltd.	2015-10-16	2021-08-25	Promoting re-epithelization of deep second degree burn	
12	Manufactured	Rosmir	Tego autologous fibroblast	Tego Science, Inc.	2017-12-27	2021-08-24	Improvement of moderate-to-severe nasojugal groove	
13	Manufactured	Cartilife	Basol autologous cartilage derived chondrocyte	Biosolution Co., Ltd.	2019-04-24	2021-07-22	Treatment of knee cartilage defect (ICRSgrade III or IV, defect area 2 to 10 cm^2)	

* Detailed approval information (efficacy/effectiveness, administration/dosage, and precautions for use) is available at http://nedrug.mfds.go.kr

2) Approval Status of Gene Therapy Agents

1 item was newly approved as gene therapy agent in 2023 after 3 items were approved in 2021 (refer to Table 47).

“Carvykti injection (Ciltacabtagene autoleucel)” (Jassen Korea, approved on March 16, 2023) is an autologous chimeric antigen receptor T-cell (CAR-T) therapy that targets B-cell maturation antigen (BCMA), which is expressed at high levels on a patient's multiple myeloma cells, to specifically kill cancer cells. It is indicated for the treatment of relapsed or refractory multiple myeloma that has received at least four prior therapies, including proteasome inhibitors, immunomodulatory agents, and anti-CD38 antibodies.

Table 47. List of Approved Gene Therapy Agents (2021~2023)

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/Effectiveness	Remark
1	Imported	Kymriah	Tisagenlecleucel	Novartis Korea	2021-03-05	1. Treatment of leukemia relapsed after transplantation or secondary relapse and subsequent relapsed leukemia or refractory B-cell acute lymphoblastic leukemia (ALL) in pediatric patients up to 25 years of age and young adult patients 2. Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more systemic therapies 3. Treatment of adult patients with follicular lymphoma(FL) that is relapsed or refractory after two or more prior therapies	New orphan drug

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/Effectiveness	Remark
2	Imported	Zolgensma Inj.	Onasemnogene abeparvovec	Novartis Korea	2021-05-28	Patient with Spinal Muscular Atrophy (SMA) with abiallelic mutation in the Survival Motor Neuron 1 (SMN1) gene falling in the any of followings: - Clinically diagnosed with Type1 - Three or less copy numbers of Survival Motor Neuron 2 (SMN2) gene	New orphan drug
3	Imported	Luxturna Inj.	Voretigene neparvovec	Novartis Korea	2021-09-09	Treatment of adults and children who have lost vision due to inherited retinal dystrophy caused by biallelic RPE65 mutation and have sufficient viable retinal cells	Orphan drug
4	Imported	Carvykti injection	ciltacabtagene autoleucel	Jassen Korea	2023-03-16	Treatment of relapsed or refrac-tory multiple myeloma that has received at least 4 prior therapies, including proteasome inhibitors, immunomodulatory agents, and anti-CD38 antibodies	Orphan drug

4

Approval Status of Herbal(Oriental) Medicines

4. Approval Status of Herbal (Oriental) Medicines

In 2023, 10 items of herbal (oriental) medicines were approved (refer to Table 48).

Analyzing by review type, 7 items were a drug requiring data submission with a change in strength, new administration/dosage and new dosage form (same administration route). In addition, there were 2 items exempted from safety/efficacy based on its existence in a foreign compendium and 1 item approved based on the prescription in Korean traditional herbal medicine books.

Table 48. Herbal (oriental) Medicines Approved in 2023 by Review Type

(Unit: Number of items)

<table>
<tr><th>Type</th><th colspan="3">Review Type</th><th colspan="2">Number of Approved Items</th></tr>
<tr><td>1</td><td rowspan="2">New Drugs (0)</td><td colspan="2">New Drugs</td><td colspan="2">0</td></tr>
<tr><td>2</td><td colspan="2">New Orphan Drugs</td><td rowspan="2">Orphan Drugs (0)</td><td colspan="2">0</td></tr>
<tr><td>3</td><td colspan="2">Orphan Drugs</td><td colspan="2">0</td></tr>
<tr><td>4</td><td colspan="3">Drugs requiring data submission</td><td colspan="2">7</td></tr>
<tr><td>4-1</td><td colspan="3">Incrementally modified drugs</td><td colspan="2">0</td></tr>
<tr><td>4-2-1</td><td rowspan="9">Drugs requiring data submission</td><td colspan="2">Injections and transdermal absorption preparations falling under ETC without prescription basis</td><td rowspan="9">7</td><td>0</td></tr>
<tr><td>4-2-2</td><td colspan="2">Single or combination agents with new composition and specification</td><td>0</td></tr>
<tr><td>4-2-3</td><td colspan="2">Single agent with change in strength</td><td>4</td></tr>
<tr><td>4-2-4</td><td colspan="2">Combination agent with change in strength</td><td>0</td></tr>
<tr><td>4-2-5</td><td colspan="2">Drugs with new efficacy/effectiveness</td><td>0</td></tr>
<tr><td>4-2-6</td><td colspan="2">Drugs with new administration/dosage</td><td>1</td></tr>
<tr><td>4-2-7</td><td colspan="2">Drugs with new route of administration</td><td>0</td></tr>
<tr><td>4-2-8</td><td colspan="2">Single or combination agents based on literature including Korean traditional herbal medicine books</td><td>0</td></tr>
<tr><td>4-2-9</td><td colspan="2">New dosage form with same administration route</td><td>2</td></tr>
<tr><td>5</td><td colspan="3">Equivalence demonstration</td><td colspan="2">0</td></tr>
<tr><td rowspan="2">6</td><td rowspan="2">Others</td><td colspan="2">Exemption from safety and efficacy data submission</td><td rowspan="2">3</td><td>2</td></tr>
<tr><td colspan="2">Prescription in Korea traditional medicine books</td><td>1</td></tr>
</table>

When categorizing according to the drug classification criteria, 5 items were ETC, 6 items were OTC and all of which were manufactured items (refer to Table 49).

Table 49. Herbal Medicinal(oriental) Medicines Approved in 2023

(Unit: Number of Items)

Type	Category	Total	Item Approval			
			ETC	OTC	Drug Substances	Medicinal Herbs
Total		10	5	5	0	0
Herbal medicinal products, etc.	Manufactured	10	5	5	0	0
	Imported	0	0	0	0	0

4.1 Approval Status of New Herbal Medicinal(oriental) Products

There have been no new herbal medicinal(oriental) products since 2014, but one domestically developed new herbal medicinal(oriental) product was approved in 2021 and no new drug was approved in 2022 and 2023 (refer to Table 50).

Table 50. Approval Status of New Herbal (Oriental) Products by Year (2010~2023)

(Unit: Number of items)

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Manufactured	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Imported	2	0	0	1	0	0	0	0	0	0	0	0	0	0

4.2 Approval Status of Herbal Medicinal(oriental) Products Requiring Data Submission

The herbal medicinal(oriental) products requiring data submission approved in 2023 include 4 items with change in strength, 1 item with new administration/dosage, and 2 items with new dosage form (same administration route) (refer to Table 51).

Table 51. Drugs Requiring Data Submission Approved in 2023

(Unit: Number of items)

Review Type of Drugs Requiring Data Submission	Number of Approved Items
Change in strength	4
New efficacy/effectiveness, administration/ dosage	1
New dosage form	2
Total	7

4.2.1. Drugs with change in strength (4 items)

4 items (4 manufactured items) with change in strength were approved via lowering strength to improve patient compliance (refer to Table 52).

4 items including **“MINIMACOR soft capsule(Omega-3-acid ethyl esters 90)”** (Dasan Pharmaceutical Co., Ltd., approved on March 10, 2023) have been developed to improve complience by diminishing the capsule size with previous high strength Omega-3-acid ethyl esters 90 capsule reduced from 1000 mg to 500 mg.

Table 52. Drugs Requiring Data Submission with Change in Strength Approved in 2023

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
1	Manufactured	MINIMACOR soft capsule (Omega-3-acid ethyl esters 90)	Dasan Pharmaceutical Co., Ltd.	2023-03-30	Anti-arteriosclerotic drug	Omega-3-acid ethyl esters 90
2	Manufactured	Mini Mega Soft Cap. 500mg	GL Pharma	2023-03-30	Anti-arteriosclerotic drug	Omega-3-acid ethyl esters 90
3	Manufactured	Newmaron Soft Capsule 0.5g	THERAGEN ETEX CO., LTD.	2023-03-30	Anti-arteriosclerotic drug	Omega-3-acid ethyl esters 90
4	Manufactured	Newmacor s soft capsule 500mg (Omega-3-acid ester 90)	Yuyu Pharma	2023-03-23	Anti-arteriosclerotic drug	Omega-3-acid ethyl esters 90

4.2.2. Drugs with New administration/dosage (1 item)

1 item was approved as new administration/dosage (1 manufactured item) was approved through preparation improvement (refer to Table 53).

“Join F Tab.” (SK Chemicals Co., Ltd., approved on December 21, 2023) improved patient compliance by reducing the frequency of dosing from three times daily to twice daily.

Table 53. Drugs Requiring Data Submission with New administration/dosage Approved in 2023

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
1	**Manufactured**	Join F Tab.	SK Chemicals Co., Ltd.	2023-12-21	Antipyretic, analgesic and anti-inflammatory agent	Clematidis Radix·Trichosanthis Radix·Prunellae Spica 30% Ethanol Dry Extract (40→1)

4.2.3. Drugs with New Dosage Form (Same Administration Route) (2 Items)

2 items with new dosage form (2 manufactured items) were approved. “Kyungbang Maekmundongtang Soft Extract“ (KYUNGBANG Pharma ceutical Co.,Ltd, approved on October 20, 2023) was approved with change of dosage form from granules to extract and “Kyungbang Eungyosan Soft Extract“ was approved with change of dosage form from liquid to extract (refer to Table 54).

Table 54. Approval Status of Drugs Requiring Data Submission with New Dosage Form in 2023

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredients
1	Manufactured	Kyungbang Maekmundongtang Soft Extract	KYUNGBANG Pharmaceutical Co.,Ltd.	2023-10-20	Antitussives	Oryzae semen, ginseng, licorice, jujube, liriope tuber, pinellia tuber
2	Manufactured	Kyungbang Eungyosan Soft Extract	KYUNGBANG Pharmaceutical Co.,Ltd.	2023-12-01	Antipyretic analgesic and anti-inflammatory agent	Lonicera Flower, platycodon root, forsythia fruit, licorice, schizonepeta spike, gazellae seu saigae cornu, glycine semen preparatum, lophatheri herba, mentha herb, arctium fruit

4.3 Approval Status of Other Herbal Medicinal(oriental) Products

Among miscellaneous herbal medicinal products approved in 2023, 3 OTC drugs were domestically manufactured.

“Ginsenside Cap. (Ginseng 40% Ethanol Dry Extract)” (RICHWOOD TRADING COMPANY, LTD., approved on March 29, 2023) was exempt

from submitting safety and efficacy data since the drugs are already listed in a foreign compendium despite not having existing approval and is approved for the purpose of improving physical and mental fatigue during and after illness(during suffering from illness and after recovery), weakness, exhaustion, and difficulty concentrating.

“Kwangdong Chimokgo” (Kwangdong Pharm Co., Ltd., approved on February 16, 2023) was exempt from submitting safety and efficacy data since the drugs are already listed in a foreign compendium despite not having existing approval and is approved for use in the treatment of loss of appetite, physical fatigue, weak constitution, decreased physical strength after illness, gastrointestinal weakness, poor blood color, cold, and developmental period.

“Gwimyeonggo” (HANPOONG PHARM. Co., Ltd., approved on December 21, 2023) is a formulation of the prescription in Korean traditional herbal medicine books (Bangyakhappyeon, one of Korean traditional herbal medicine book) and is approved for use in the course of illness and post-illness, weak constitution, physical fatigue, lethargy, and menopausal disorders.

4.4 Approval Status of Drug Substances and Medicinal Herbs

There was no item approved as the drug substance for herbal medicinal(oriental) products and medicinal herbs.

Appendix Status of the Departments in Charge of Civil Petition for Drugs, etc.

Table 53. Status of the Departments in Charge of Civil Petition for Drugs, etc. (As of April 2024)

Category	Department	Detailed Petition Service
Director for Approval Management		·Approval of drugs for manufacturing/marketing and import ·Management related to drug review and approval system ·Registration of DMF ·Classification of drugs ·Review of range of pharmacy preparations and medical institution dispensary preparations ·Improvement of approval/review system ·Enactment/amendment of guidelines related to approval ·General management of preliminary review of approval/ notification
Director for Novel Product Approval		·Approval of biopharmaceuticals, recombinant protein products, advanced biopharmaceutical products and quasi-drugs for manufacturing/ marketing and import ·Approval of manufacture and importation by product type and classification of medical devices (only applicable to Class Ⅰ·Ⅱ devices subject to approval and Class III/IV devices) ·Classification and approval of products in which drugs, quasi-drugs and medical devices are chemophysically combined (combination products) ·Operation of approval system for biologics, quasi-drugs, medical devices and combination products ·Orders of re-review on medical devices
Pharma-ceutical Safety Bureau	Pharmaceutical Policy Division	·Designation of orphan drugs ·Registration and management of the drug patent list ·Operation of drug patent-approval linkage (approval of priority of sales, etc.)
	Pharmaceutical Management Division	·Drug labeling ·Renewal of drugs
	Pharmaceutical Safety Evaluation Division	·Re-evaluation and re-review of drugs ·Risk management plan
	Pharmaceutical Quality Division	·GMP evaluation and guidance of drugs ·Inspection of drug substances (DMF)

Category	Department		Detailed Petition Service
	Clinical Trials Policy Division		·Approval of clinical trial plans ·Inspection of clinical trials ·Management of institutions for clinical and non-clinical (GLP) trials.
	Narcotics Policy Division		·Approval of manufacture and import/export businesses and products of narcotic drugs. ·Quality management of narcotic drugs ·Designation of temporary narcotics
	Narcotics Management Division		·Follow-up management of narcotics
National Institute of Food and Drug Safety Evaluation	Pre-Submission Consultation Division		·Pre-submission consultation for the approval of clinical trial plan for new drugs and drugs that are subject to expedited review (including biopharmaceuticals, recombinant protein products and herbal medicinal products) ·Pre-submission consultation on the approval for new drugs and drugs that are subject to expedited review ·Pre-submission consultation on the approval for clinical trial plan for medical devices that are subjects of expedited review (excluding digital health devices and in vitro diagnostic devices) ·Pre-submission consultation on the approval for medical devices that are subject to expedited review ·Pre-submission consultation and review support for clinical statistics data ·Operation of a preliminary review system for drugs, etc.
	Expedited Review Division of Medicine and Medical Devices		·Review of applications for designation of drugs (including biopharmaceuticals, recombinant protein products, herbal medicinal products) that are subjects to expedited review ·Review of applications for designation of medical devices (excluding digital health devices and in vitro diagnostic devices) that are subject to expedited review ·Expedited review of quality and safety/efficacy of drugs that are designated for expedited review ·Expedited review of technical documents and clinical trial data of medical devices that are designated for expedited review ·Preliminary review of drugs and medical devices under the jurisdiction (excluding previously approved items) ·Enactment/amendment of instructions/guidelines related to expedited review
	Drug Evaluation	Pharmaceutical Standardization	·Review of registration data of drug substances (excluding substances of new drugs)

Category	Department		Detailed Petition Service
	Department	Division	·Generic drug quality review ·Review of equivalence test data on the revision (addition) of the active substance manufacturer without changes in the manufacturing method for the drugs under the jurisdiction
		Cardiovascular and Neurology Products Division	110 Drugs for central nervous system 120 Drugs for peripheral nervous system 130 Drugs for sensory organs 190 Miscellaneous drugs for nervous system and sensory organs 210 Circulatory system drugs 264 Drugs for pain-relieving, antipruritic, convergence, antiinflammatory 300 Metabolic drugs (excluding miscellaneous metabolic drugs (390)) 799 Drugs not classified separately and not primarily used for treatment 800 Narcotics ·Safety/efficacy review ·Review of clinical trial plans ·Preliminary review ·Re-evaluation, re-review, and review of RMP periodic report
		Oncology and Antimicrobial Products Division	140 Antiallergic drugs 220 respiratory drugs 240 Hormone drugs (including anti-hormonal agents) 250 Urogenital and anal organ drugs 260 Dermatologic drugs (excluding 264, 267, and 268) 290 Miscellaneous drugs for individual organs 400 Drugs for functional activation of tissue cells 600 Anti-pathogenic biological drugs (excluding 630) 720 Drugs for diagnosis 730 Drugs for public hygiene ·Safety/efficacy review ·Review of clinical trial plans ·Preliminary review · Review of re-evaluation, re-review and risk management plan data

Category	Department		Detailed Petition Service
		Advanced Drug Quality Division	·Review of the quality of new drugs, orphan drugs, drugs requiring data submission, etc. ·Review of registration data of drug substances (new substances and its salts) ·Quality review of clinical trial plans ·Quality review of drugs included in combination products ·Quality review of radiopharmaceuticals ·Preliminary review on quality of drugs under the jurisdiction ·Review of equivalence test data on the revision (addition) of the active substance manufacturer without changes in the manufacturing method for the drugs under the jurisdiction
		Bioequivalence Evaluation Division	·Review of bioequivalence test plan ·Review of bioequivalence test result report ·Review of reliability of bioequivalence test ·Re-evaluation of bioequivalence test ·Review of drug equivalence test result report (approval/notification of manufactured(imported) items (post-approval/notification changes included). ·Review of drug equivalence test result report (approval/notification) ·Safety/efficacy review and review of clinical trial plans of digestive system drugs (230) ·Safety/efficacy review and review of clinical trial plans of miscellaneous metabolic drugs (390) ·Preliminary review ·Review of re-evaluation of re-review result report ·Periodic reports and results of risk management plan, and PSUR reviews
Biopharma-ceuticals and Herbal Medicine Bureau	Biological Product Policy Division (Advanced Biological Products TF)		GMP evaluation for advanced biological products ·GMP evaluation ·Review of re-evaluation/re-review/review of risk management plan data
	Biopharmaceutical Quality Management Division		·GMP evaluation and guidance for manufacturers and manufactured/imported items such as biologics ·Inspection of active pharmaceutical ingredients (DMF) that are subject to notification of human placenta-derived drugs ·Re-review and re-evaluation of biologics

Category	Department		Detailed Petition Service
			·Risk management plan
	Herbal Medicine Policy Division		·Preliminary GMP evaluation for herbal medicines
	Cosmetics Policy Division		·GMP evaluation for cosmetics, etc.
	Quasi-drug Policy Division		·GMP evaluation for quasi-drug
National Institute of Food and Drug Safety Evaluation	Biopharma-ceuticals and Herbal Medicine Evaluation Department	Biologics Division	Biologics and human placenta-derived drugs ·Quality and safety/efficacy review ·Review of clinical trial plans ·Preliminary review ·Review of re-evaluation and re-review data
		Recombinant Protein Products Division	Recombinant protein products ·Quality and safety/efficacy review ·Review of clinical trial plans ·Preliminary review ·Review of re-evaluation and re-review data
		Cell and Gene Therapy Products Division	Advanced biological products ·Quality and safety/efficacy review ·Review of clinical trial plans ·Preliminary review ·Review of re-evaluation and re-review data
		Herbal Medicinal Products Division	Herbal(oriental) medicinal products, etc. ·Quality and safety/efficacy review ·Review of drug equivalence (including bioequivalence test) ·Review of clinical trial plans ·Preliminary review ·Review of re-evaluation and re-review data
		Cosmetics Evaluation Division	Functional cosmetics ·Quality and safety/efficacy review ·review of supporting documents of cosmetics labelling/ advertisement Quasi-drugs ·Quality and safety/efficacy review ·Preliminary review ·Review of re-evaluation data

2023 Drug Approval Report

Date of Publication	June 2024		
Publisher	Yukyoung Oh		
Editor in Chief	Sangbong Kim		
Editors	Youngjoo Kim,	Kisuk Kim,	Younsu Kim,
	Joonho Bang,	Jihye Lee,	Nari Woo,
	Sukyung Ahn,	Sunyeong Yang,	Kyeorye Lee,
	Jiyeong Lee,	Yoonjung Huh,	Jiyeon Choi,
	Wonhee Kim,	Suji Hong,	Hyunjoon Hwang,
	Namyun Kim,	Geunah Lee,	Jongsook Park,
	Naye Shin,	Songwon Jeon,	Heejung Jung,
	Eeray Kim	Taeho Kim	Minjeong Park,
	Hyemin Kim	Mirae Kim	Juok Kim
	Insun Lee	Jongduk Na	Songe Ham
	Haejin Kim	Hyunyoung Lee	
	(Biopharmaceutical	Approval TF)	
	Hyunjung Park,	Naery Lee,	Moa Jeong,
	Heajeong Doh,	Youngki Hong,	Sanghwa Ryu,
	Mi Ae Kim,	Jihye Park	Ahreum Jo,
	Seongyi Kwon,	Seonlim Choi	
Organization	Pharmaceutical Approval Management Division, Ministry of Food and Drug Safety		

Introduction of Public Interest Reporter Protection System

The Public Interest Reporter Protection Act always protects your conscience.
If a public official or representative of the Ministry of Food and Drug Safety has committed an irregularity or handled any issue unfairly, please report it as follows. We guarantee the identity of the reporter and promise to do our best to ensure that there is no inconvenience in handling civil complaints in the future.

What is Public Interest Reporter Protection System?
A system for protecting public interest reporters, etc. (including relatives or partner) through **confidentiality, disadvantage protection measures, personal protection measures,** etc. so that they are not harmed by public interest reports, etc.

※ How to request protection measures
Ministry of Food and Drug Safety website (www.mfds.go.kr) > National Communication > National Sinmungo > Public Official Corruption Report