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2022 Drug Approval Report

June 2023

Ministry of Food and Drug Safety

Director for Approval Management

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General Status of 2022 Drug Approval and Notification

1. General Status of 2022 Drug Approval and Notification

The 2022 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 2021 Drug Approval Report.

1.1. General Status

The 1,636 items were approved and notified in 2022, as shown in Table 1, including chemical drugs, biologics and herbal medicinal products. The total number of items decreased by around 29.1% (634 items) compared to the previous year, and in particular, the number of approved and notified manufacturing items and items of Regional FDS decreased by 29.0% (609 items) and 47.7% (845 items), respectively. The decrease seems to be attributed to the decline in generic drug approvals due to the limitation on the number of approved items for the joint use of clinical trial (bioequivalence test) data, introduced in July 2021.

Approved items accounted for 1,081 items (66.1%) and notified ones took up 555 items (33.9%) of the total (1,636 items).

According to the institution-specific analysis of the total, 710 items (43.4%) were approved by the MFDS and 926 items (56.6%) were approved and notified by the Regional FDS, which indicates that the number of items approved and notified by the Regional FDS decreased than that of the previous year, while that of approved items by the MFDS increased.

According to manufactured/imported item category, domestically manufactured and marketed items were 1,490 items (91.1%), whereas imported ones accounted for 146 items (8.9%), indicating that the number of domestically

manufactured items remains high compared with that of the imported items for all its slightly increasing year-on-year.

Drug products accounted for 1,451 items (87.7%), drug substances 76 items (4.6%), and medicinal herbs 109 items (6.7%), which indicates that the proportion of drug products was the same as the previous year without any significant change, and the proportions of drug substances and medicinal herbs showed some changes.

The proportions of drug products and drug substances were 95.0% (1,451 items) and 5.0% (76 items), respectively, when excluding medicinal herbs, with drug products accounting for the majority, and 75.6% were ETC drugs (1,097 items), and 24.4% were OTC drugs (354 items) among the drug products.

Table 1. Drug Approval and Notification Overview (2019-2022)

(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
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 (38 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 2022 decreased by 29.9% compared to 2021, reaching 1,081 items. The notification items decreased by 26.6% when including medicinal herbs, and 20.8% at the time of excluding medicinal herbs, compared to 2021, whereby the corresponding number is 555 items and 446 items, respectively.

In the case of medicinal herbs, they were all notified items (109 items) in 2022, which showed a significant decrease (44.1%) than that of 2021 (195 items).

Table 2-1. Number of Drugs Approved and Notified Annually (Including Medicinal Herbs)

(Unit: Number of items)

Category	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Approval	835	1,423	1,811	2,110	2,036	1,315	1,379	3,691	2,319	1,514	1,081
(Year-on-year increase, %)		70.4%	47.3%	16.6%	-3.5%	-35.4%	4.9%	167.7%	-37.2%	-34.7%	-29.9%
Notification	3,898	973	1,296	2,813	1,792	1,209	1,103	2,496	1,177	756	555
(Year-on-year increase, %)		-75.0%	33.2%	117.1%	-36.3%	-32.5%	-8.8%	126.3%	-52.8%	-35.8%	-26.6%
Total	4,733	2,396	3,107	4,923	3,828	2,524	2,482	6,187	3,496	2,270	1,636
(Year-on-year increase, %)		-49.4%	29.7%	58.4%	-22.2%	-34.1%	-1.7%	149.3%	-43.5%	-35.1%	-27.9%

* Excluding drugs for export, including revoked/withdrawn items

Table 2-2. Number of Drugs Approved and Notified Annually (Excluding Medicinal Herbs)

(Unit: Number of items)

Category	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Approval	831	1,423	1,811	2,110	2,030	1,306	1,378	3,684	2,315	1,512	1,081
(Year-on-year increase, %)		71.2%	27.3%	16.6%	-3.8%	-35.7%	5.5%	167.3%	-37.2%	-34.7%	-29.9%
Notification	687	787	1,118	904	815	798	743	1,196	983	563	446
(Year-on-year increase, %)		14.6%	42.1%	-19.1%	-9.8%	-2.1%	-6.9%	61.0%	-17.8%	-42.7%	-20.8%
Total	1,518	2,210	2,929	3,014	2,845	2,104	2,121	4,880	3,298	2,075	1,527
(Year-on-year increase, %)		45.6%	32.5%	2.9%	-5.6%	-26.0%	8.1%	130.1%	-32.4%	-37.1%	-26.4

Table 2-3. Number of Medicinal Herbs Notified Annually

(Unit: Number of items)

Category	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Medicinal herbs	3,211	186	178	1,909	983	420	361	1,307	198	195	109
(Year-on-year increase, %)		-94.2%	-4.3%	972.5%	-48.5%	-57.3%	-14.0%	262.0%	-85.2%	-1.5%	-44.1%

* Excluding drugs for export, including revoked/withdrawn items

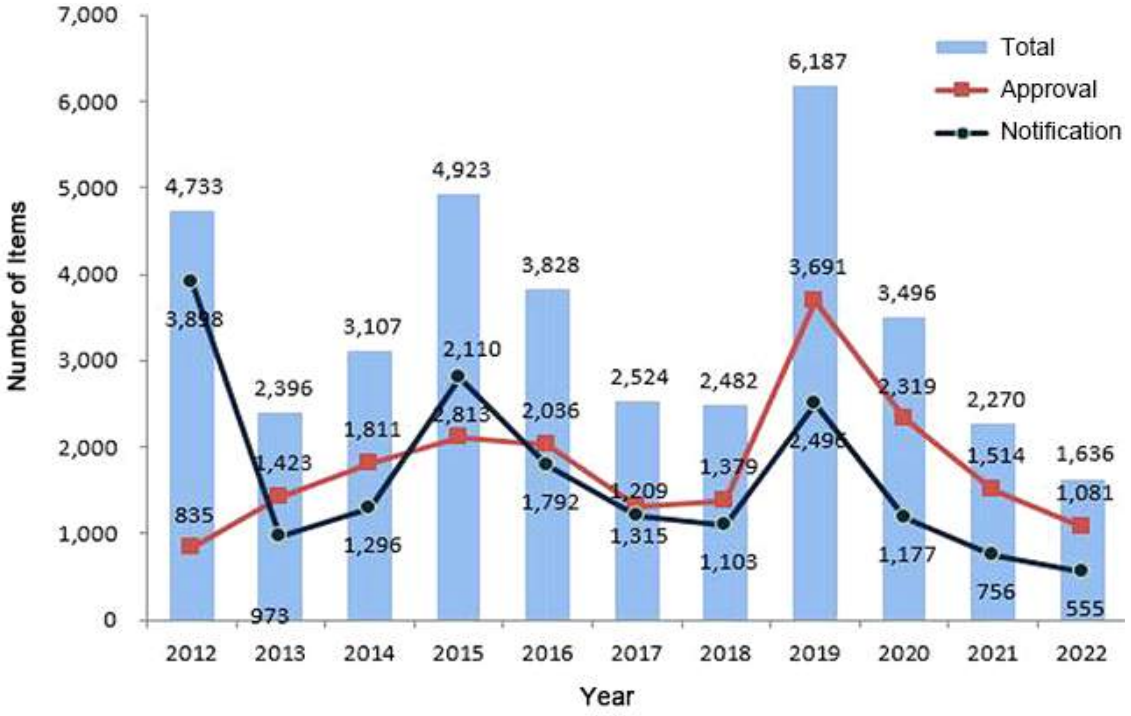

Figure 1-1. Number of Approved and Notified Drugs (2012-2022)
(Including Medicinal Herbs)

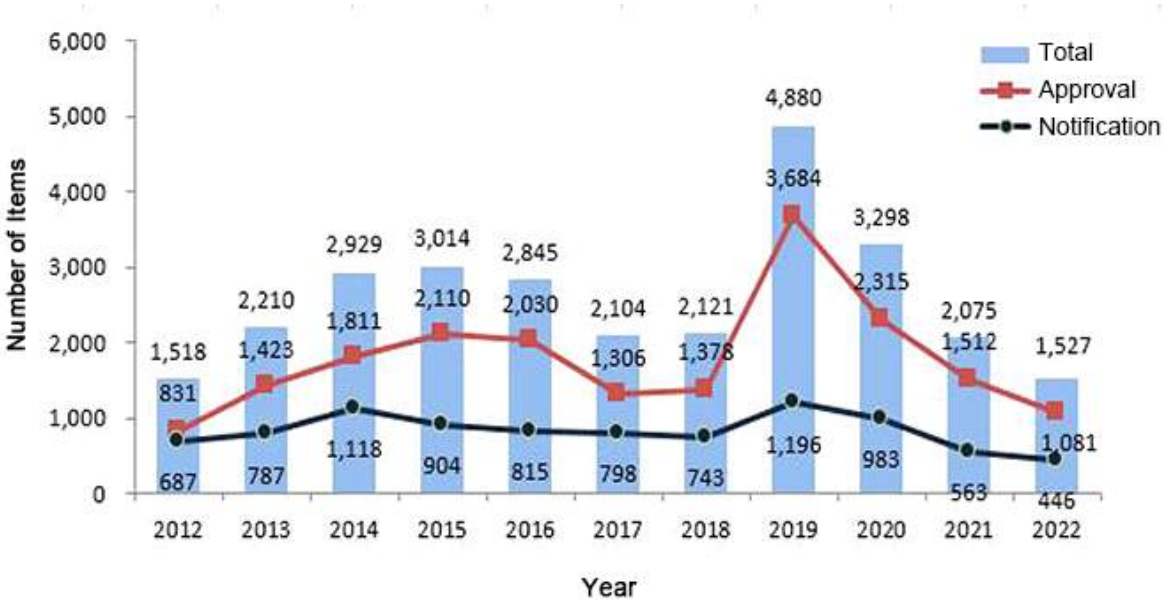

Figure 1-2. Number of Approved and Notified Drugs (2012-2022)
(Excluding Medicinal Herbs)

The institution-specific analysis (Table 3-1) of the drug approval and notification in 2022 shows that the regional FDS approved 371 items (34.3%) while the MFDS approved 710 items (65.7%) of the total 1,081 approved items, showing that the number of items approved by the MFDS is double that of the Regional FDS. It is attributed to the sharp decrease in the number of generic drug items approved by the regional FDS whereas that of the approved items by the MFDS remained at a similar level to the previous one.

Table 3-1. 2022 Drug Approval and Notification by Institution

(Unit: Number of items)

Category	Total	MFDS	Regional FDS
Approval	1,081 (100%)	710 (65.7%)	371 (34.3%)
Notification	446	0	446
Medicinal Herbs	109	0	109
Total	1,636 (100%)	710 (43.4%)	926 (56.6%)

* Excluding drugs for export (38 items), including revoked and withdrawn items and medicinal herbs

Drug products made up 97.8% (1,351 items) and drug substances 2.2% (30 items) of the domestically manufactured items while drug products 68.5% (100 items) and drug substances 31.5% (46 items) of the imported items, in which the drug products occupied a larger portion than the drug substances. In particular, despite the decrease in the number of items approved by the Regional FDS, the majority of manufactured items were drug products, which was contributing to similar level to the previous year (refer to Table 3-2).

Table 3-2. 2022 Drug Approval and Notification Overview

(Unit: Number of items)

<table>
<tr><th colspan="4">Domestically Manufactured (1,381 items)</th><th colspan="4">Imported (146 items)</th></tr>
<tr><td rowspan="6">Drug Products (1,351) 97.8%</td><td rowspan="3">ETC (1,006) 72.8%</td><td rowspan="2">Approval (963)</td><td>MFDS (600)</td><td rowspan="6">Drug Products (100) 68.5%</td><td rowspan="3">ETC (91) 62.3%</td><td rowspan="2">Approval (89)</td><td>MFDS (82)</td></tr>
<tr><td>Regional FDS (363)</td><td>Regional FDS (7)</td></tr>
<tr><td>Notification (43)</td><td>Regional FDS (43)</td><td>Notification (2)</td><td>Regional FDS (2)</td></tr>
<tr><td rowspan="3">OTC (345) 25.0%</td><td rowspan="2">Approval (16)</td><td>MFDS (15)</td><td rowspan="3">OTC (9) 6.2%</td><td rowspan="2">Approval (3)</td><td rowspan="2">MFDS (3)</td></tr>
<tr><td>Regional FDS (1)</td></tr>
<tr><td>Notification (329)</td><td>Regional FDS (329)</td><td>Notification (6)</td><td>Regional FDS (6)</td></tr>
<tr><td colspan="2" rowspan="2">Drug Substances (30) 2.2%</td><td>Approval (4)</td><td>MFDS (4)</td><td colspan="2" rowspan="2">Drug Substances (46) 31.5%</td><td>Approval (6)</td><td>MFDS (6)</td></tr>
<tr><td>Notification (26)</td><td>Regional FDS (26)</td><td>Notification (40)</td><td>Regional FDS (40)</td></tr>
</table>

* Excluding drugs for export (38 items) and medicinal herbs (109 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 (87.7%) of the total number were Gyeongin FDS, Daejeon FDS and Seoul FDS, with the rate of 43.7% (405 items), 25.5% (236 items) and 18.5% (171 items) respectively. For medicinal herbs notification, the three regions that accounted for the majority of the total number were Seoul FDS, Gwangju FDS, and Daegu FDS, with the rate of 77.1% (84 items), 17.4% (19 items) and 4.6% (5 items) respectively (see Table 4).

Table 4. Details of 2022 Drug Approval and Notification by the Regional FDS

(Unit: Number of items)

Category		Approval	Notification	Medicinal Herbs	Total
Regional FDS	Gyeongin	233 (62.8%)	172 (38.6%)	0 (0%)	405 (43.7%)
	Daejeon	91 (24.5%)	144 (32.3%)	1 (0.9%)	236 (25.5%)
	Daegu	5 (1.3%)	16 (3.6%)	5 (4.6%)	26 (2.8%)
	Gwangju	9 (2.4%)	46 (10.3%)	19 (17.4%)	74 (8%)
	Seoul	29 (7.8%)	58 (13%)	84 (77.1%)	171 (18.5%)
	Busan	4 (1.1%)	10 (2.2%)	0 (0%)	14 (1.5%)
Total		371 (100%)	446 (100%)	109 (100%)	926 (100%)

* Excluding drugs for export (38 items), including revoked and withdrawn items and medicinal herbs

Regarding the approval and notification for manufactured and imported items, the approved items took the higher proportion than the notified items. In the case of manufactured items, the approved items (66.0%) were more than the notified items (34.0%) by 32.0%. For imported items, the rate proportion of approved items (67.1%) were more than double that of notified items (32.9%) (refer to Table 5).

Table 5. Manufactured and Imported Drugs Approved in 2022

(Unit: Number of items)

Category	Total	Manufactured	Imported
Approval	1,081	983 (66.0%)	98 (67.1%)
Notification	555	507 (34.0%)	48 (32.9%)
Total	1,636	1,490 (100%)	146 (100%)

* Excluding drugs for export (38 items), including revoked and withdrawn items and medicinal herbs

Regarding the approval and notification for drug products and drug substances, in the case of the drug products, approved items accounted for 73.8% (1,071 items), and notified items 26.2% (380 items). In the case of drug substances (Excluding medicinal herbs), approved items accounted for 13.2% (10 items) and notified items 86.8% (66 items). The approved items accounted for most of the drug products and the notified items accounted for most of the drug substances (refer to Table 6).

Table 6. Details of Drug Products and Substances Approved and Notified in 2022

(Unit: Number of items)

Category	Total	Drug Product	Drug Substance (including medicinal herbs)	Drug Substance (excluding medicinal herbs)
Approval	1,081	1,071 (73.8%)	10 (5.4%)	10 (13.2%)
Notification	555	380 (26.2%)	175 (94.6%)	66 (86.8%)
Total	1,636	1,451 (100%)	185 (100%)	76 (100%)

* Excluding drugs for export (38 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 the types of drug products, among approved and notified items, chemical drugs accounted for the majority at 92.7% (1,345 items), herbal medicinal products took up 3.9% (57 items), and biologics 3.4% (49 items) (refer to Table 7).

Table 7. Classification of Chemical Drugs, Biologics, Advanced Biopharmaceutical Products and Herbal Medicinal Products within Drug Products in 2022

(Unit: Number of items)

Category	Total[1]	Chemical Drugs[2]	Biologics[3]	Advanced Biopharma-ceutical Products[4]	Herbal Medicinal Products[5]
Drug Product	1,451	1,345 (92.7%)	49 (3.4%)	0 (0.0%)	57 (3.9%)

1) Excluding drugs for export (38 items), including revoked/withdrawn items
2) Out of 1,345 items, 644 items were approved by the MFDS.
3) All items were approved by the MFDS (Excluding Advanced Biopharmaceutical Products)
4) All items were approved by the MFDS.
5) Out of 57 items, 7 items were approved by the MFDS.

Regarding drug products approved and notified by review type, new drugs (including new orphan drugs) accounted for 1.9% (28 items), orphan drugs (excluding orphan new drugs) 1.7% (24 items), drugs requiring data submission

(including incrementally modified drugs; IMDs) 41.0% (595 items), and generic drugs 55.4% (804 items), of which generic drugs accounted for the largest proportion. Among drugs requiring data submission, 9 chemical drugs were certified as incrementally modified drugs (IMDs) developed with either new composition, or new therapeutic class (refer to Table 8).

Table 8. Classification of Drug Products by Review Type in 2022

(Unit: Number of items)

Category	Type (Total)	New Drugs		Orphan Drugs	Drugs Requiring Data Submission		Others (generics, etc.)		
		New Drugs	New Orphan Drugs	Orphan Drugs	IMDs	Drugs Requiring Data Submission	Herbal (Oriental) Medicinal Products Based on Herbal Medicine Books	(MFDS)	(Regional FDS)
Drug Product	Chemical drugs 1,345	17	1	21	9	549	-	47[4]	701[5]
	Biologics 49[6]	6	4	3	0	36	-	-	-
	Advanced biopharma-ceutical products 0	-	-	-	-	-	-	-	-
	Herbal medicinal products 57	-	-	-	-	1	7	4	45
Total	1,451[1] (100%)	23	5[3]	24 (1.7%)	9	586	7	51	746
		28[2] (1.9%)			595 (41.0%)		804 (55.4%)		

1) Excluding drugs for export (38 items), including revoked/withdrawn items
2) 28 items were approved as new drugs in 2022, excluding designated new drugs (2 items) through post-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 biopharmaceutical products

In addition, majority of the drug products approved by the MFDS were chemical drugs (644 items, 92.0%), followed by biologics (49 items, 7.0%) and herbal medicinal products (7 items, 1.0%). And no advanced biopharmaceutical products were approved. Chemical drugs and herbal medicinal products were mostly approved as manufactured items, but in the case of biologics, imported items (33 items) were approved more than twice as much as manufactured items (16 items) (refer to Table 9).

Table 9. Details of Drug Product Approved (by the MFDS) in 2022

(Unit: Number of items)

Type	Total	Manufactured	Imported
MFDS Approval (Drug Product)	700	615	85
Chemical Drugs	644 (92.0%)	592	52
Biologics	49 (7.0%)	16	33
Advanced Biopharmaceutical Products	0 (0.0%)	0	0
Herbal medicinal products	7 (1.0%)	7	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 75.6% (1,097 items), which was three times more than OTC drugs 24.4% (354 items). In addition, the number of approved drug products (1,071 items) was approximately three times higher than that of notified items (380 items) (refer to Table 10).

Table 10. Detailed Overview of 2022 Drug Product Approval

(Unit: Number of items)

Category	Total	ETC	OTC
Total	1,451 (100%)	1,097 (75.6%)	354 (24.4%)
Approval	1,071 (100%)	1,052 (98.2%)	19 (1.8%)
Notification	380 (100%)	45 (11.8%)	335 (88.2%)

* Excluding drugs for export (38 items) and medicinal herbs (109 items), including revoked and withdrawn items

Based on anlysis of the annual trends of each drug type approved and notified, 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 after 2020, which is presumed to be due to the trend of decrease in generic drugs following the limitation on the number (3 times) of joint use of clinical (bioequivalence test) study data.

Specifically, 1,097 ETC drugs, 354 OTC drugs, 76 drug substances and 109 medicinal herbs were approved in 2022, showing decrease in number by 28.9% (1,542 items), 21.3% (450 items), 8.4% (83 items) and 27.9% (195 items) compared to 2021, respectively (refer to Table 11 and Figure 2).

Table 11. Number of Approvals and Notifications by Drug Type (2013-2022) (Including revoked and withdrawn items)

(Unit: Number of items)

Category	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
ETC Drugs	1,669	2,090	2,289	2,280	1,573	1,514	4,139	2,525	1,542	1,097
(Year-on-year increase, %)		25.2%	9.5%	-0.4%	-31.0%	-3.8%	173.4%	-39.0%	-38.9%	-28.9%
OTC Drugs	427	726	626	481	476	532	670	704	450	354
(Year-on-year increase, %)		70.0%	-13.8%	-23.2%	-1.0%	11.8%	25.9%	5.1%	-36.1%	-21.3%
Drug substances	114	113	99	84	55	75	71	69	83	76
(Year-on-year increase, %)		- 0.9%	-12.4%	-15.2%	-34.5%	36.4%	-5.3%	-2.8%	20.3%	-8.4%
Medicinal Herbs	186	178	1,909	983	420	361	1,307	198	195	109
(Year-on-year increase, %)		- 4.3%	972.5%	-48.5%	-57.3%	-14.0%	262.0%	-84.9%	-1.5%	-27.9%
Total	2,396	3,107	4,923	3,828	2,524	**2,482**	**6,187**	**3,496**	**2,270**	**1,636**

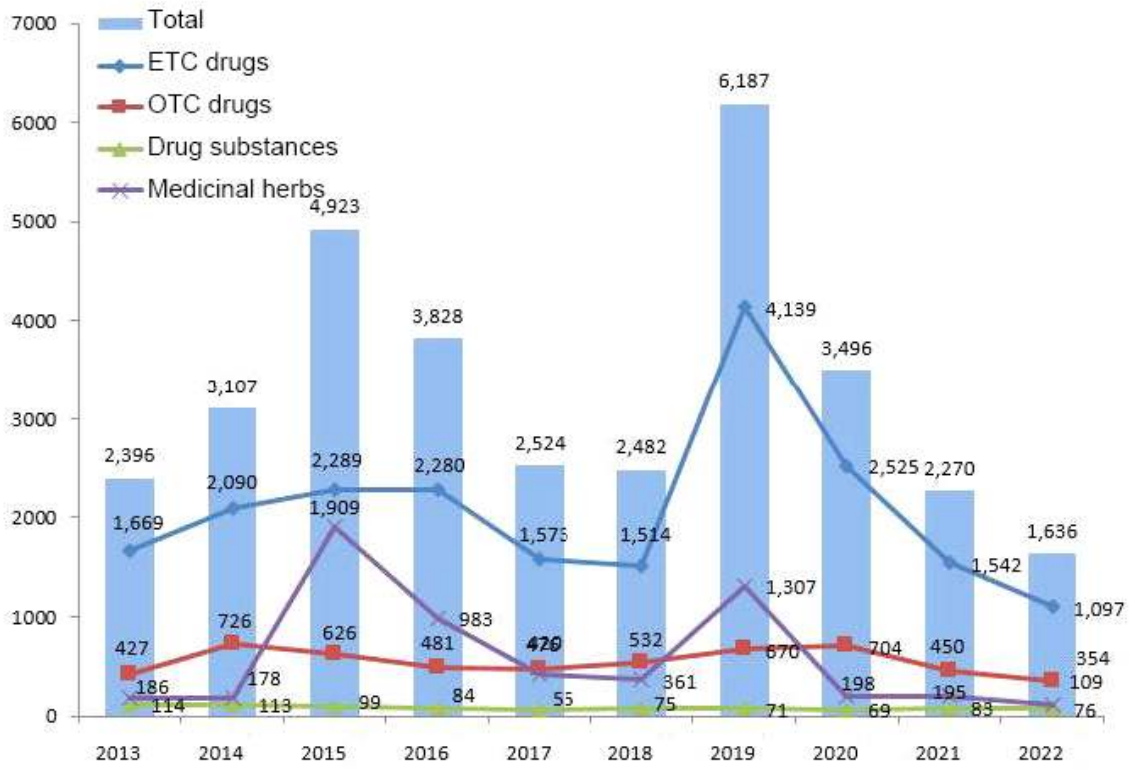

Figure 2. Approval and Notification Status by Drug Type (2013-2022)

1.2. Approval of New Drugs

New drugs newly approved and designated in 2022 were 30 items in total including 20 chemical drugs (5 manufactured items and 15 imported items) and 10 biologics (2 manufactured items and 8 imported items). There were no approved new drugs for advanced biopharmaceutical products and herbal medicinal products. New drugs containing 22 new drug ingredients were approved, which were composed of 13 ingredients from chemical drugs and 9 ingredients from biologics. Compared to domestically manufactured new drugs (7 items), the number of approved items and ingredients of imported new drugs (23 items) accounted for three times more, indicating that most of the new substances were developed as imported new drugs (Table 12, refer to Table 15 for full list of new drugs).

Table 12. New Drugs Approved in 2022

(Unit: Number of items)

Category	Total [Number of Ingredients]	Chemical Drugs	Biologics	Advanced Biopharma-ceutical Products	Herbal Medicinal Products
Total	30[1] (100.0%) [22 (100.0%)]	20[2] [13]	10 [9]	0 [0]	0 [0]
Manufactured	7 (23.3%) [5 (22.7%)]	5 [3]	2 [2]	0 [0]	0 [0]
Imported	23 (76.7%) [17 (77.3%)]	15 [10]	8 [7]	0 [0]	0 [0]

1) Out of 30 items, 5 items were designated as both orphan and new drug.

2) In 2022, 18 items of chemical drugs were newly approved, and 2 items were designated as new drugs as per the post-approval changes (refer to Table 15).

Comparing the new drug approvals by year, the number of new drugs (30 items) approved in 2022 decreased from that of approved items (37 items) in 2021. 76.7% of new drugs were imported items, similar to the previous year (78.4%), showing that the majority of new drugs were still imported (refer to Table 13-1, Figure 3).

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), and 2 items were developed domestically in 2022. The number of new imported chemical drugs decreased by 4 items compared to the previous year, and the number of manufactured biologics decreased by 1 item, contributing to the similar one to the previous year. The decrease in new drug approvals in 2022 is due to the decrease in new imported chemical drugs (refer to Table 13-2).

Table 13-1. New Drugs Approved Annually (2011-2022) (Including revoked and withdrawn items)

(Unit: Number of items)

Category	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Manufac-tured	8 (25.8%)	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%)
Imported	23 (74.2%)	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%)
Number of Items	31	17	23	49	34	25	29	15	35	40	37	30

Table 13-2. Approval of Chemical Drugs, Biologics, Advanced Biopharmaceutical Products and Herbal medicinal products as New Drugs Annually (2011-2022) (Including revoked and withdrawn items)

(Unit: Number of items)

Category		2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Number of Approved Items[1)] (Number of new drug ingredients)		31 (22)	17 (14)	23 (15)	49 (27)	34 (19)	25 (10)	29 (18)	15 (12)	35 (21)	40 (20)	37 (28)	30 (22)
Chemical Drugs	New drugs developed in Korea	2	2	1	1	5	1	1	2	0	0	2	1
	Manufac-tured	8	3	3	3	6	2	1	2	4	5	4	5
	Imported	17	10	13	38	18	19	16	9	24	29	19	15
Biologics	New drugs developed in Korea	0	0	0	0	0	0	1	0	0	0	2	1
	Manufac-tured	0	0	0	0	0	0	1	0	0	0	3	2
	Imported	6	4	6	8	10	4	11	4	7	6	8	8
Advanced Biopharma-ceutical Products	New drugs developed in Korea	-	-	-	-	-	-	-	-	-	-	0	0
	Manufac-tured	-	-	-	-	-	-	-	-	-	-	0	0
	Imported	-	-	-	-	-	-	-	-	-	-	2	0
Herbal medicinal products	New drugs developed in Korea	0	0	0	0	0	0	0	0	0	0	1	0
	Manufac-tured	0	0	0	0	0	0	0	0	0	0	1	0
	Imported	0	0	1	0	0	0	0	0	0	0	0	0

1) The number of new drugs approved in the corresponding year including items designated as new drugs as per the post-approval changes (2 chemical drugs)

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

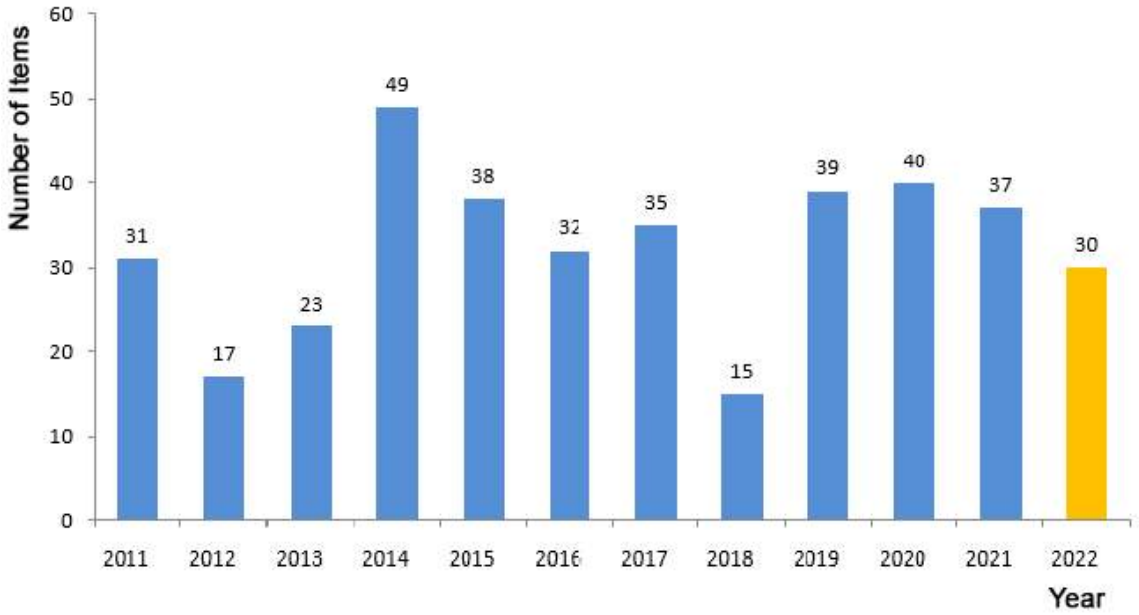

Figure 3. Number of New Drugs Approved Annually (2011-2022) (Including revoked, withdrawn , post-approval changed items) [Refer to Table 15]

Regarding the new drug approval status after 2010 by therapeutic class, 6 items (3 ingredients) of genitourinary system drugs in 2011, 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 and 8 items (4 ingredients) of anti-diabetes agents 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 accounted for the majority. From 2019 to 2021, anti-tumor agents accounted for the majority, with 13 items (5 ingredients) in 2019, 13 items (6 ingredients) in 2020, and 6 items (6 ingredients) in 2021 approved, respectively. In 2022, circulatory system agents accounted for the highest rate with 7 items (3 ingredients), and the cumulative number of new drug approvals over the past 12 years could be arranged in descending order: anti-tumor agents (89 items), nervous system drugs (53 items), and anti-diabetes agents (33 items),

followed by chemotherapeutic agents (31 items) and circulatory system drugs (31 items) (refer to Table 14).

Table 14. Therapeutic Class of New Drug Approved Annually (2011-2022)

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

(Unit: Number of items)

Category	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022		Total
												Approval	Post-approval change	
Nervous system	0	1	1	16	8	2	0	0	9	9	6	2	0	53
Anti-tumor agents	3	6	4	7	5	14	11	1	13	13	6	4	2	89
Anti-diabetes	3	1	6	11	8	0	0	2	0	0	0	2	0	33
Chemotherapeutic agents	1	1	0	2	5	2	3	4	4	5	0	4	0	31
Circulatory system	3	0	0	1	2	6	9	1	0	3	4	2	0	31
Respiratory system	1	0	0	4	1	2	1	0	1	0	2	0	0	12
Genitourinary system	6	0	2	0	0	0	0	0	0	0	0	1	0	9
Sensory system	1	2	0	3	0	0	0	0	3	0	1	0	0	10
Anti-allergic Drugs (including certified therapeutic agents)	1	2	3	1	0	0	8	2	1	3	3	2	0	26
Others	12	4	7	4	9	6	3	5	8	7	16	11	0	92
Total	31	17	23	49	38	32	35	15	39	40	37	28	2	386
												30		

Table 15. List of New Drugs Approved in 2022

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

☐ Chemical Drugs, ☐ Biologics

No.	Manufactured /Imported	Product Name	Company	Date of Approval (Designation)	Classification	Efficacy/Effectiveness (partially omitted)
1	Imported	Lorviqua tablet 25 mg (lorlatinib)	Pfizer Pharmaceutical Korea Limited	(Revoked from the orphan drug list, switched as new drug on 2022-05-11) *Initial Approval Date: 2021-07-29	Anti-tumor agents	Treatment of adult patients with anaplastic lymphoma kinase(ALK) positive metastatic non-small cell lung cancer (NSCLC)
2	Imported	Lorviqua tablet 100 mg (lorlatinib)				
3	Manufactured	NUVAXOVID Pre-filled Syringe (SARS-CoV-2 surface antigen vaccine (recombinant))	SK bioscience Co., Ltd.	2022-01-12	Vaccines	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older
4	Imported	Vocabria tablet 30 mg (cabotegravir sodium)	GSK Korea	2022-02-03	Miscellaneous chemotherapeutic agents	Combination therapy with rilpivirine tablets for short-term treatment of HIV-1 infection in adult patients who are virologically suppressed (HIV-1 RNA < 50 copies/mL), have no history of treatment failure, and have no known or suspected resistance to cabotegravir or rilpivirine - Oral lead-in to assess tolerability of cabotegravir prior to administration of long-acting cabotegravir and rilpivirine injection - Oral therapy for patients seeking to temporarily alternate cabotegravir and rilpivirine injection therapy
5	Imported	Vocabria Injection (cabotegravir)				
6	Imported	Epclusa Tablet	Gilead Sciences Korea Ltd.	2022-02-17	Miscellaneous chemotherapeutic agents	Treatment of adults and pediatric patients aged 12 years or older and weighing 30 kg or more who were infected with genotypes 1, 2, 3, 4, 5, or 6 chronic hepatitis C virus (HCV) using this drug or in combination with ribavirin

No.	Manufactured /Imported	Product Name	Company	Date of Approval (Designation)	Classification	Efficacy/Effectiveness (partially omitted)
7	Imported	Vosevi Tablet	Gilead Sciences Korea Ltd.	2022-03-23	Miscellaneous chemotherapeutic agents	Among adult patients with chronic Hepatitis C virus (HCV) infection without hepatocirrhosis or with compensated hepato-cirrhosis (Child-Pugh A) - Treatment of patients with genotypes 1, 2, 3, 4, 5, or 6 chronic HCV infection who were treated with HCV therapy including NS5A inhibitors - Treatment of patients with genotype 1a or type 3 chronic HCV infection who were treated with HCV therapy including sofosbuvir without NS5A inhibitors
8	Imported	Jyseleca Film-coated Tablets 100 mg(filgotinib maleate)	Eisai Korea Inc.	2022-04-01	Certified therapeutic agents (including non-specific immunosuppre-ssant)	Treatment of moderate to severe active rheumatoid arthritis in adults who do not respond adequately or have no tolerability to one or more disease-modifying anti-rheumatic drugs (DMARDs) This drug can be administered alone or in combination with methotrexate (MTX). This drug is not used with biologic disease-modifying anti-rheumatic drugs (bDMARDs) or other Janus kinase (JAK) inhibitors.
9	Imported	Jyseleca Film-coated Tablets 200 mg (filgotinib maleate)				
10	Imported	Inrebic Capsule (fedratinib hydrochloride hydrate)	BMS Pharmaceutical Korea Ltd.	2022-04-27	Anti-tumor agents	Treatment of splenomegaly or symptoms associated with the following diseases in adult patients previously treated with ruxolitinib - Primary myelofibrosis - Myelofibrosis after polycy-themia vera - Myelofibrosis after essential thrombocythemia There are no data proving the efficacy of this drug in therapeutic confirmatory studies.

No.	Manufactured /Imported	Product Name	Company	Date of Approval (Designation)	Classification	Efficacy/Effectiveness (partially omitted)
11	Imported	Ozempic Pre-filled Pen (Semaglutide)	Novo Nordisk Pharma Korea, Ltd.	2022-04-28	Antidiabetics	This drug is administered as an adjunct to diet and exercise therapy in adults with insufficient control of type 2 diabetes. - monotherapy - combination with other anti-diabetes agents It is administered to reduce the risk of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke) in adult patients with type 2 diabetes and confirmed cardiovascular disease.
12	Imported	Reblozyl Injection 25 mg (Luspatercept)	BMS Pharmaceutical Korea Ltd.	2022-05-09	Miscellaneous blood and body fluid drugs	1. Treatment of adult patients exhibiting the following symptoms with anemia who require red blood cell transfusion due to an inadequate response to or unsuitable for erythro-poiesis- stimulating agent (ESA) therapy - Lowest-risk, low-risk, moderate-risk myelodysplastic syn-dromes with ring sideroblasts (MDS-RS) - Lowest-risk, low-risk, moderate-risk myelodysplastic syn-dromes and myelo-proliferative neoplasm with ring sideroblasts and myeloproliferative tumor (MDS/MPN-RS-T) 2. Treatment of adult patients with beta thalassemia requiring red blood cell transfusion
13	Imported	Reblozyl Injection 75 mg (Luspatercept)				
14	Imported	Kerendia Tablet 10 mg (finerenone)	Bayer Korea Ltd.	2022-05-10	Miscellaneous circulatory system drugs	Reducing the risk of persistent decrease in estimated glomerular filtration rate (eGFR), reaching end-stage renal disease, death from cardiovascular disease, hospitalization due to non-fatal myocardial infarction and heart failure in patients with chronic kidney disease
15	Imported	Kerendia Tablet 20 mg (finerenone)				

No.	Manufactured /Imported	Product Name	Company	Date of Approval (Designation)	Classification	Efficacy/Effectiveness (partially omitted)
16	Imported	REYVOW Tablet 50 mg (lasmiditan hemisuccinate)	ILDONG PHARMACEUTICAL CO.,LTD.	2022-05-11	Antipyretics, analgesics, and anti-inflammatory drugs	acute treatment of migraine with or without aura
17	Imported	REYVOW Tablet 100 mg (lasmiditan hemisuccinate)				
18	Imported	Bexsero	GSK Korea	2022-05-19	Vaccines	Prevention of invasive meningococcal disease caused by Neisseria meningitidis group B in 2 months or older
19	Manufactured	SkyCovione Multi Injection (SARS-CoV-2 surface antigen vaccine (recombinant))	SK bioscience Co., Ltd.	2022-06-29	Vaccines	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older
20	Imported	Ceprotin Injection (Human protein C)	Takeda Pharmaceuticals Co., Ltd.	2022-08-02	Blood products	Prevention and treatment of venous thrombosis and purpura fulmina in pediatric and adult patients with severe congenital protein C deficiency
21	Imported	Enhertu Injection 100 mg (trastuzumab deruxtecan)	Daiichi Sankyo Korea Co., Ltd.	2022-09-19	Anti-tumor agents	1. Treatment of patients with unresectable or metastatic HER2-positive breast cancer who have previously received one or more anti - HER2 -based treatments 2. Treatment of patients with locally advanced or meta -static HER2-positive gastric or gastroesophageal junction adenocarcinoma who have previously received two or more treatments, including anti-HER2 regimen
22	Imported	Poteligeo Injection 20 mg (mogamulizumab)	Kyowa Kirin Korea Co., Ltd	2022-09-22	Anti-tumor agents	Treatment of adult patients with Mycosis Fungoides or Sézary syndrome who have previously received one or more systemic therapy

No.	Manufactured /Imported	Product Name	Company	Date of Approval (Designation)	Classification	Efficacy/Effectiveness (partially omitted)
23	Imported	Akynzeo Injection	HK inno.N corporation	2022-10-31	Emetics and antiemetics	Adult 1. Prevention of acute and delayed nausea and vomiting induced by initial and repeated treatment with severe anti-cancer chemotherapeutic agents induced emesis 2. Prevention of acute and delayed nausea and vomiting induced by initial and repeated treatment with moderate emetogenic anti-cancer chemotherapeutic agents induced emesis
24	Manufactured	Beova Tablet 50 mg (vibegron)	JEIL PHARMACEUTICAL CO., LTD.	2 022-10-31	Miscellaneous urogenital and anal organ drugs	Treatment of symptoms of urinary urgency, urinary frequency and urge incontinence of overactive bladder
25	Manufactured	ENAROY Tablet 4 mg (enarodustat)	JW Pharmaceutical	2022-11-17	Miscellaneous blood and body fluid drugs	Treatment of symptomatic anemia in adult patients with chronic kidney disease undergoing hemodialysis
26	Manufactured	ENAROY Tablet 1 mg (enarodustat)				
27	Manufactured	ENAROY Tablet 2 mg (enarodustat)				
28	Manufactured	Envlo Film-coated Tablets 0.3 mg (enavogliflozin)	Daewoong Pharmaceuticals	2022-11-30	Antidiabetics	This drug is administered as an adjunct to diet and exercise therapy to improve blood sugar control in patients with type 2 diabetes. - Monotherapy - Combination therapy
29	Imported	Jemperli Injection (dostarlimab)	GSK Korea	2022-12-14	Anti-tumor agents	Treatment of adult patients exhibiting recurrent or progressive mismatch repair deficient (dMMR)/high frequency microsatellite instability-high (MSI-H) endometrial cancer during or after treatment with previous platinum-based systemic chemotherapy

No.	Manufactured /Imported	Product Name	Company	Date of Approval (Designation)	Classification	Efficacy/Effectiveness (partially omitted)
30	Imported	Zavicefta Injection 2 g/0.5 g (ceftazidime/avibactam)	Pfizer Pharmaceutical Korea Limited	2022-12-22	Acting mainly on gram-negative bacteria	1. Indication - Treatment of complicated intraperitoneal infection (cIAI) in adults and pediatric patients aged 3 months or older(can be used in combination with metronidazole) - Treatment of complicated urinary tract infections (cUTI) including pyelonephritis in adults and pediatric patients aged 3 months or older - Treatment of hospital-acquired pneumonia(HAP) including ventilator-associated pneumonia(VAP) in adult patients aged 18 years or older 2. Effective for: - Complex intraperitoneal infection: Gram-negative bacteria: Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa. - Complex urinary tract infection: Gram-negative bacteria : Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterobacter cloacae, Pseudomonas aeruginosa. - Hospital-acquired pneumonia, including ventilator-associated pneumonia : Gram-negative bacteria : Enterobacter cloacae, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Serratia marcescens, Pseudomonas aeruginosa.

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

Table 16. List of New Drugs Developed in Korea (1999-2022) (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 29 items of orphan drugs were approved in 2022 (including 5 new orphan drugs), in which 3 manufactured and 21 imported items, and 22 chemical drugs and 7 biologics were approved. Additionally, 22 ingredients were approved, which is composed of 16 ingredients of chemical drugs, and 6 ingredients of biologics (refer to Table 17).

Table 17. Orphan Drugs Approved in 2022

(Unit: Number of items)

Category	Total (number of ingredients)	Chemical Drugs	Biologics	Advanced Biopharma-ceutical Products	Herbal Medicinal Products
Manufactured	3 (2)	3 (2)	0 (0)	0 (0)	0 (0)
Imported	21 (16)	18 (13)	3 (3)	0 (0)	0 (0)
New Orphan Drugs	5 (4)	1 (1)	4 (3)	0 (0)	0 (0)
Total	29 (22)	22 (16)	7 (6)	0 (0)	0 (0)

The status of orphan drug approvals since 2010 shows that the number of approved items was similar until 2014, but 49 items were approved in 2015, which was 1.8 times larger than the five-year average (27 items). After 2016, orphan drug approval was on the decline, with 34 items approved in 2016, 18 items in 2017, 17 items in 2018, and 11 items in 2019. 28 items were approved in 2020, 22 items in 2021, and 29 items in 2022 (refer to Table 18, Figure 4).

Table 18. Number of Orphan Drugs Approved Annually (2011-2022)

(Including revoked and withdrawn items)

(Unit: Number of items)

Category	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Approval	26	27	28	28	49	34	18	17	11	28	22	**29**

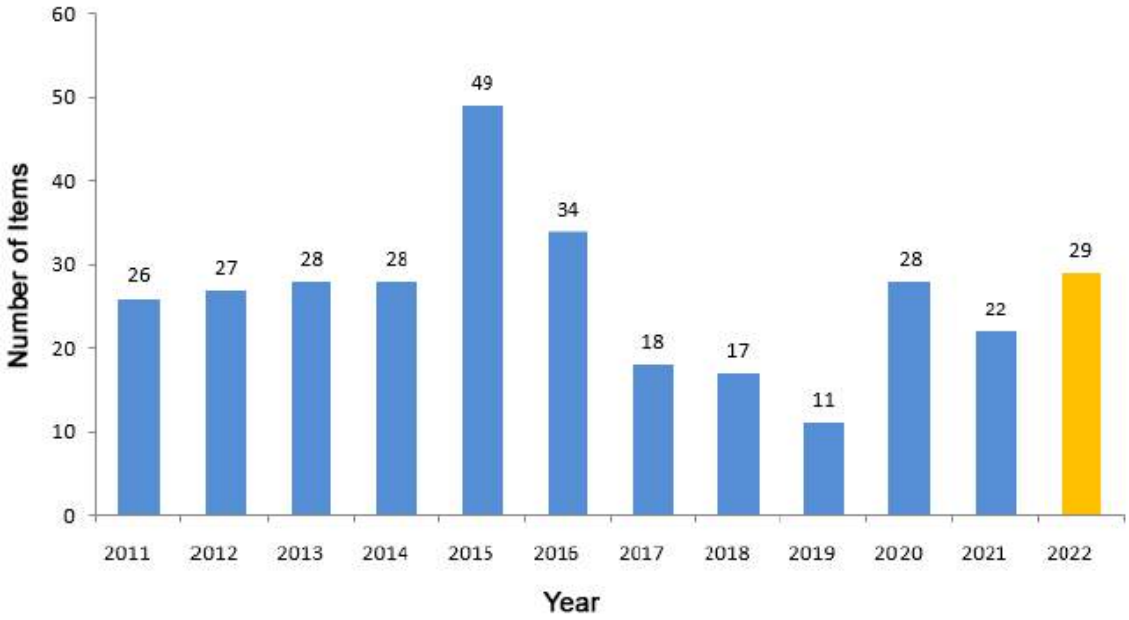

Figure 4. Number of Orphan Drugs Approved (2011-2022)

In addition, a total of 31 ingredients were newly designated as orphan drugs in 2022 (refer to Table 19).

Table 19. Ingredients of Newly Designated Orphan Drugs in 2022

No.	Ingredient (generic name)	Indication
1	Tafasitamab (Injection)	Relapsed or refractory diffuse large B-cell lymphoma in adult patients who are not eligible for autologous hematopoietic stem cell transplantation and who have failed one or more prior treatments. Combination therapy with lenalidomide
2	Maralixibat (syrup)	Cholestatic pruritus in patients with Alagille's syndrome
3	Caplacizumab (injection)	Acquired thrombotic thrombocytopenic purpura
4	Teclistamab (injection)	Recurrent or refractory multiple myeloma which received at least three treatments, including proteasome inhibitors, immunomodulators and anti-CD38monoclonal antibodies
5	Olipudase alfa (injection)	Acid sphingomyelinase deficiency (ASMD)
6	Elranatamab (injection)	Relapsed or refractory multiple myeloma in adults who were previously treated with three regimens containing at least one proteasome inhibitor, immunomodulator, and anti-CD38 antibody
7	Belzutifan (tablet)	Adult VHL that does not require immediate surgery but requires treatment for von Hippel-Lindau (VHL)-associated renal cell carcinoma, central nervous system hemangioblastoma, or pancreatic neuroendocrine tumor
8	Recombinant human epidermal cell growth factor (injection)	Wagner grade 3-4 diabetic foot ulcer
9	Sutimlimab (injection)	Cold agglutinin disease
10	Velmanase alfa (injection)	Alpha-mannosidosis
11	Mavacamten (oral)	Treatment of symptomatic obstructive hypertrophic cardiomyopathy in adults
12	Niraparib/ abiraterone acetate (tablet)	Metastatic castration-resistant prostate cancer with a homologous recombination repair gene mutation
13	Soticlestat (tablet)	Dravet syndrome and Lennox-Gastaut syndrome
14	Avacopan (capsule)	Combination therapy with rituximab or cyclophosphamide for the treatment of adult patients with symptomatic severe granulomatous polyangiitis (GPA) or microscopic polyangiitis (MPA)
15	Iptacopan (capsule)	Paroxysmal nocturnal hemoglobinuria
16	Glofitamab (injection)	Adult patients with recurrent or refractory diffuse large B-cell lymphoma after two or more systemic treatments
17	Macimorelin acetate (granule)	Diagnosis of adult growth hormone deficiency
18	Mosunetuzumab (injection)	Adult patients with recurrent refractory follicular lymphoma after two or more systemic treatments
19	Tagraxofusp (injection)	Adult patients with blast cell plasmacytoid dendritic cell tumors who have not been treated previously
20	Zolbetuximab (injection)	CLDN18.2-positive and HER2-negative unresectable locally advanced or metastatic gastric adenocarcinoma or gastroesophageal junction adenocarcinoma in adult patients (in combination with fluoropyrimidine-based and platinum-based chemotherapy as first-line treatment)
21	Zilucoplan (injection)	Generalized myasthenia gravis in patients with anti-acetylcholine receptor antibody positive

No.	Ingredient (generic name)	Indication
22	Belumosudil mesylate (Tablet)	Chronic graft-versus-host disease in adults and pediatric patients aged 12 years or older who have failed two or more previous systemic therapies
23	Eladocagene exuparvovec (injection)	Clinically, molecularly, and genetically diagnosed aromatic L-amino acid decarboxylase deficiency with a severe phenotype in pediatric patients aged 18 months or older
24	Delandistrogene moxeparvovec (injection)	Duchenne muscular dystrophy
25	Talquetamab (injection)	Relapsed or refractory multiple myeloma treated with at least one proteasome inhibitor, immunomodulator, and anti-CD38 antibody in three previous regimens
26	Budesonide (capsule)	Adult IgA nephropathy with a urinary protein to creatinine ratio greater than or equal to 1.5 g/g
27	Pegcetacoplan (injection)	Paroxysmal nocturnal hemoglobinuria
28	Ivosidenib (tablet)	Adult patients who are newly diagnosed with acute myeloid leukemia with IDH1 mutation, who are aged 75 years or older, or with a comorbidity not suitable for intensive induction chemotherapy (in combination with azacitidine) Locally advanced or metastatic cholangiocarcinoma with IDH1 mutation previously treated in adult patients
29	Allergen extract (injection)	Immunotherapy and allergy diagnosis for bee sting allergy
30	Thiotepa (injection)	Used in combination with other chemotherapy in the following cases: - Pre-treatment therapy prior to allogeneic or autologous hematopoietic stem cell transplantation for hematologic diseases in adults and pediatric patients, regardless of whether whole body irradiation is concurrently performed or not - When high-dose chemotherapy is appropriate along with hematopoietic stem cell transplantation for the treatment of solid cancer in adult and pediatric patients
31	Efgartigimod alfa (injection)	Generalized myasthenia gravis in adults

1.4. Approval and Notification Status by Major Therapeutic Class

In descending order, the ratio of drug products approved and notified in 2022 by therapeutic class are as follows: metabolic drugs such as anti-diabetes agents, etc. (43.3%), nervous system drugs such as antipyretics, analgesics, and anti-inflammatory drugs, etc. (15.7%), circulatory system drugs such as anti-hypertensive drugs, etc. (8.3%), digestive system drugs such as stomach ulcer drugs, etc. (5.9%), anti-allergic drugs such as antihistamines, etc. (2.5%) (refer to Table 20 and Figure 5).

Table 20. Number of Approved and Notified Items by Therapeutic Class in 2022 (Including revoked and withdrawn items)

(Unit: Number of items)

<table>
<tr><th rowspan="2">Thera-peutic dass
Total</th><th rowspan="2">Nervous System</th><th rowspan="2">Circulatory System</th><th rowspan="2">Digestive System</th><th colspan="2">Metabolism</th><th rowspan="2">Sensory Organ Drugs</th><th rowspan="2">Tumor Drugs</th><th rowspan="2">Dermato-logic Drugs</th><th rowspan="2">Anti-allergi c</th><th rowspan="2">Others</th></tr>
<tr><th>Others</th><th>Anti-diabetics</th></tr>
<tr><td rowspan="2">1,451</td><td rowspan="2">228
(15.7%)</td><td rowspan="2">120
(8.3%)</td><td rowspan="2">85
(5.9%)</td><td>30
(2.1%)</td><td>599
(41.3%)</td><td rowspan="2">29
(2.0%)</td><td rowspan="2">32
(2.2%)</td><td rowspan="2">28
(1.9%)</td><td rowspan="2">37
(2.5%)</td><td rowspan="2">263
(18.1%)</td></tr>
<tr><td colspan="2">629
(43.3%)</td></tr>
</table>

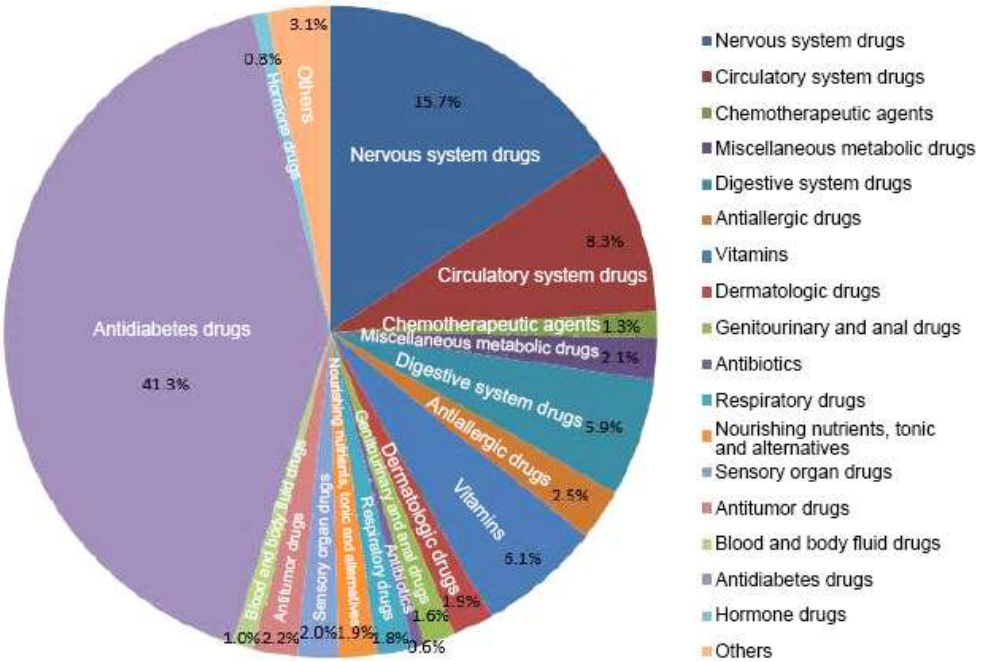

Figure 5. Distribution Status of Approved and Notified Drugs by Major Therapeutic Class in 2022

According to the analysis of the approval and notification status by therapeutic class annually, circulatory system drugs, metabolic drugs (including antidiabetics), nervous system drugs, and digestive system drugs accounted for the majority in 2022 as it did in 2021. The approved/notified drugs that accounted for the largest proportion in 2022 were antidiabetics (41%), which increased by 24% compared to 2021. The approved/notified drugs with the second largest proportion were the nervous system drugs, most of which were antipyretics, analgesics, anti-inflammatory drugs, autonomic nervous system drugs, and psychotropics (refer to Figure 6 and Table 22).

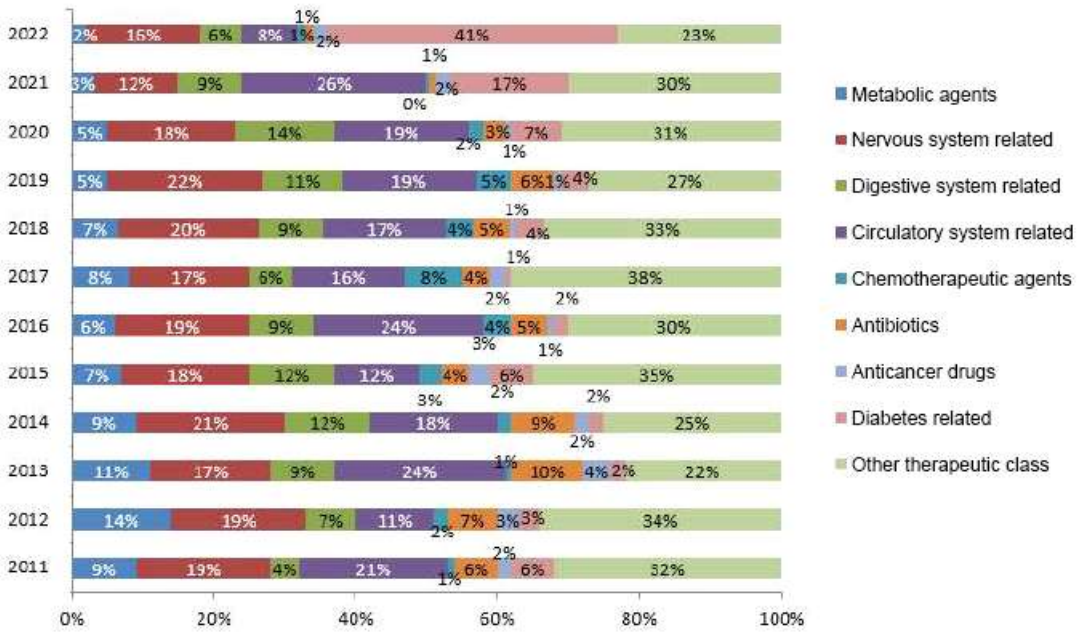

Figure 6. Ratio of Approved and Notified Drugs by Drug Therapeutic Class Annually (2011-2022)

Further analyzing by efficacy, it is shown that 599 items (41.3%) of antidiabetics were approved, thereby occupying the most of approved items in 2022 and have been within the top 5 category since 2020. Then, 120 items (8.3%) of antipyretics, analgesics, and anti-inflammatory drugs, 67 items (4.6%)

of miscellaneous vitamin preparations, 61 items (4.2%) of miscellaneous circulatory system drugs, and 43 i2tems (3.0%) of autonomic nervous system drugs followed in order (refer to Table 21).

Table 21. Top 5 Detailed Classifications of Approved Items (2018-2022)

(Including revoked and withdrawn items)

	2018		2019		2020		2021		2022	
	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	Antipyretics, analgesics, and anti-inflammatory drugs	152 (7.4%)	Antihypertensive	482 (10.0%)	Miscellaneous circulatory system drugs	240 (7.7%)	Antiarteriosclerotic agents	377 (18.9%)	Antidiabetics	599 (41.3%)
2	Antihypertensive	145 (7.1%)	Miscellaneous central nervous system drugs	374 (7.8%)	Peptic ulcer drugs	227 (7.3%)	Antidiabetics	335 (16.8%)	Antipyretics, analgesics, and anti-inflammatory drugs	120 (8.3%)
3	Miscellaneous central nervous system drugs	128 (6.3%)	Antipyretics, analgesics, and anti-inflammatory drugs	351 (7.3%)	Antidiabetics	221 (7.1%)	Anticoagulants	160 (8.0%)	Miscellaneous vitamin preparations	67 (4.6%)
4	Antiarteriosclerotic agents	117 (5.7%)	Peptic ulcer agents	340 (7.1%)	Antipyretics, analgesics, and anti-inflammatory drugs	190 (6.1%)	Miscellaneous circulatory system drugs	123 (6.2%)	Miscellaneous circulatory system drugs	61 (4.2%)
5	Miscellaneous metabolic drugs	102 (5.0%)	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%)
	Number of drug products approved and notified in 2018	2,046 (100%)	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%)

Table 22. Drug Product Approved and Notified in 2022 by Major Therapeutic Class

Classification	Detailed Classification	Number of Items
Nervous System Drugs	General anesthetics	3
	Hypnotic sedatives	6
	Antiepileptics	12
	Antipyretics, analgesics, and anti-inflammatory drugs	120
	Stimulants, and excitants	1
	Antivertigo drugs	1
	Psychotropics	19
	Miscellaneous central nervous system drugs	18
	Local anesthetics	0
	Skeletal muscle relaxants	0
	Autonomic nervous system drugs	43
	Antispasmodics	4
	Diaphoretics, anhidrotics	1
	Subtotal	228
Ophthalmology and ENT	Ophthalmic preparations	25
	Otic and nasal agents	4
	Subtotal	29
Circulatory System Drugs, and Blood and Body Fluid drugs	Antiarrhythmic drugs	0
	Antihypertensives	28
	Capillary stabilizers	6
	Vasodilators	1
	Antiarteriosclerotic agents	24
	Miscellaneous circulatory system drugs	61
	Blood substitutes	0
	Hemostatics	2
	Anticoagulants	7
	Miscellaneous blood and body fluid drugs	6
	Subtotal	135
Respiratory Tract and Antiallergic Drugs	Antihistamines	17
	Certified therapeutic agents (including non-specific immunosuppressant)	20
	Miscellaneous antiallergic drugs	0
	Antitussive expectorants	12
	Inhalation treatment preparations	8
	Miscellaneous respiratory drugs	6
	Tuberculostatics	0
	Subtotal	63

Classification	Detailed Classification	Number of Items
Digestive System Drugs	Dental and oral drugs	4
	Peptic ulcer drugs	34
	Stomachics and digestives	6
	Antacids	4
	Emetics and antiemetics	9
	Cholagogues	0
	Probiotics	16
	Purgatives and clysters	8
	Miscellaneous digestive system drugs	4
	Subtotal	85
Urinary and Reproductive System Drugs	Uterotonic agent	1
	Emmenagogues	2
	Contraceptives	10
	Genito-urinary agents (including venereal disease preventives)	1
	Hemorrhoidal preparations	1
	Miscellaneous urogenital and anal organ drugs	8
	Subtotal	23
Metabolic Drugs	Vitamin A and D preparations	4
	Vitamin B1 preparations	1
	Vitamin B preparations (excluding vitamin B1)	4
	Vitamin C and P preparations	4
	Vitamin E and K preparations	0
	Multivitamin preparations (excluding multivitamin complex with A and D)	8
	Miscellaneous vitamin preparations	67
	Calcium preparations	5
	Mineral preparations	6
	Protein and amino acid preparations	12
	Miscellaneous nourishing nutrients, tonic and alternatives	5
	Liver disease drugs	6
	Antidotes	0
	Gout preparations	0
	Enzyme preparations	3
	Comprehensive metabolic preparations	1
	Low-content vitamin and mineral preparations	3
	Miscellaneous metabolic drugs	17
	Subtotal	146
Antidiabetic Drugs	Antidiabetics	599
	Subtotal	599
Anticancer Drugs	Anti-tumor agents	30
	Miscellaneous anti-tumor agents	2
	Subtotal	32

Classification	Detailed Classification	Number of Items
Antibiotics	Agents mainly acting on gram-positive bacteria	2
	Agents mainly acting on gram-negative bacteria	1
	Agents mainly acting on gram-positive bacteria, rickettsia, and virus	0
	Agents mainly acting on gram-positive/negative bacteria, rickettsia, and virus	2
	Agents mainly acting on gram-positive/negative bacteria	3
	Miscellaneous antibiotic drugs (including complex antibiotic drugs)	0
	Subtotal	8
Chemotherapeutics	Furan preparations	0
	Miscellaneous chemotherapeutics	19
	Subtotal	19
Others (classification that does not belong to the above therapeutic class)		84
Total		1,451

1.5. Approval Status of COVID-19 Treatments and Vaccines

There was no treatment for coronavirus disease-2019 (hereinafter referred to as "COVID-19") approved in 2022 while 8 vaccines (3 manufactured items (37.5%), 5 imported items (62.5%)) were approved (refer to Table 23).

Table 23. COVID-19 Treatments and Vaccines Approved in 2022

(Unit: Number of items)

Category	Total	COVID-19 Treatments	COVID-19 Vaccines
Total	8 (100.0%)	0	8
Manufactured	3 (37.5%)	0	3
Imported	5 (62.5%)	0	5

As for COVID-19 treatments, 2 items were approved in 2020 and 1 item in 2021 while 6 items of COVID-19 vaccines were approved in 2021 and 8 items in 2022 (refer to Table 23-1).

Table 23-1. COVID-19 Treatments and Vaccines Approved Annually (2020-2022)

Category		2020	2021	2022	Total
COVID-19 Treatments	Manufactured	0 (0.0%)	1 (14.3%)	0	1 (11.1%)
	Imported	2 (100.0%)	0 (0.0%)	0	2 (22.2%)
COVID-19 Vaccines	Manufactured	0 (0.0%)	2 (28.6%)	3 (37.5%)	5 (35.7%)
	Imported	0 (0.0%)	4 (57.1%)	5 (62.5%)	9 (64.3%)
Number of Items		2(100.0%)	7(100.0%)	8(100%)	17(100.0%)

Table 24. List of Approved COVID-19 Treatments and Vaccines

No.	Category	Product Name	Company	Active Ingredient	Efficacy/ Effectiveness	Approval Date
1	Imported	Veklury lyophilized powder for IV injection (Remdesivir)	Gilead Sciences Korea Ltd.	Remdesivir	Treatment of COVID-19	2020-07-24
2	Imported	Veklury solution for IV injection (Remdesivir)	Gilead Sciences Korea Ltd.	Remdesivir	Treatment of COVID-19	2020-07-24
3	Manufactured	Regkirona 960mg (Regdanvimab) (Regdanvimab) (monoclonal antibody, genetic recombination)	Celltrion	Regdanvimab	Treatment of COVID-19	2021-02-05
4	Manufactured	Vaxzevria solution for injection (SARS-CoV-2 virus vector vaccine)	AstraZeneca Korea	Recombinant CoV spike protein expressing adenoviral vector	Prevention of COVID-19	2021-02-10
5	Imported	Vaxzevria solution for injection (SARS-CoV-2 virus vector vaccine)				2021-05-21
6	Imported	Comirnaty Injection (Tozinameran) (SARS CoV-2 mRNA Vaccine)	Pfizer Korea Ltd.	SARS-CoV-2 spike protein expression messenger ribonucleic acid (tozinameran)	Prevention of COVID-19	2021-03-05
7	Imported	COVID-19 Vaccine Janssen (SARS-CoV-2 virus vector vaccine)	Janssen Korea Ltd.	Recombinant CoV spike protein expression adenoviral vector	Prevention of COVID-19	2021-04-07
8	Imported	Moderna Spikevax Injection (SARS-CoV-2 mRNA vaccine)	Moderna Korea Co., Ltd.	SARS-CoV-2 spike protein expression messenger ribonucleic acid	Prevention of COVID-19	2021-05-21
9	Manufactured	Spikevax Injection (SARS-CoV-2 mRNA vaccine)	Moderna Korea Co., Ltd.			2021-12-13
10	Manufactured	NUVAXOVID pre-filled syringe (SARS-CoV-2 surface antigen vaccine (recombinant))	SK bioscience Co., Ltd.	SARS-CoV-2 spike protein	Prevention of COVID-19	2022-01-12
11	Imported	Comirnaty Injection 0.1 mg/mL (Tozinameran) (SARS-CoV-2 mRNA vaccine)	Pfizer Korea Ltd.	SARS-CoV-2 spike protein expression messenger ribonucleic acid (Tozinameran)	Prevention of COVID-19	2022-01-28

No.	Category	Product Name	Company	Active Ingredient	Efficacy/ Effectiveness	Approval Date
12	Imported	Comirnaty Injection 0.1 mg/mL(5-11 Years) (Tozinameran) (SARS-CoV-2 mRNA vaccine)	Pfizer Korea Ltd.	SARS-CoV-2 spike protein expression messenger ribonucleic acid (Tozinameran)	Prevention of COVID-19	2022-02-23
13	Manufactured	SkyCovione Multi Injection (SARS-CoV-2 surface antigen vaccine (recombinant))	SK bioscience Co., Ltd.	SARS-CoV-2 spike protein RBD antigen (genetic recombination)	Prevention of COVID-19	2022-06-29
14	Imported	Moderna Spikevax 2 Injection (Elasomeran, Imelasomeran) (SARS-CoV-2 mRNA vaccine)	Moderna Korea Co., Ltd.	SARS-CoV-2 spike protein expressing messenger ribonucleic acid (Elasomeran), SARS-CoV-2 spike protein expressing messenger ribonucleic acid (Imelasomeran)	Prevention of COVID-19	2022-09-08
15	Manufactured	SPIKEVAX BIVALENT (Elasomeran, Imelasomeran) (SARS-CoV-2 mRNA vaccine)	Moderna Korea Co., Ltd.	SARS-CoV-2 spike protein expressing messenger ribonucleic acid (Elasomeran), SARS-CoV-2 spike protein expressing messenger ribonucleic acid (Imelasomeran)	Prevention of COVID-19	2022-10-07
16	Imported	Comirnaty 2 Injection 0.1mg/mL (Tozinameran,riltozinameran)(SARS-CoV-2 mRNA vaccine)	Pfizer Pharmaceuticals Korea Limited	SARS-CoV-2 spike protein expression messenger ribonucleic acid (Tozinameran), SARS-CoV-2 spike protein expression messenger ribonucleic acid (Riltozinameran)	Prevention of COVID-19	2022-10-07
17	Imported	Comirnaty Injection 0.1 mg/mL (6 Months - 4 Years) (Tozinameran) (SARS-CoV-2 mRNA vaccine)	Pfizer Pharmaceuticals Korea Limited	SARS-CoV-2 spike protein expression messenger ribonucleic acid (Tozinameran)	Prevention of COVID-19	2022-11-25

2

Approval Status of Drugs (Chemical Drugs)

2. Approval Status of Drugs (Chemical Drugs)

Regarding the chemical drugs approved in 2022 by the review type, it is found that 20 new drugs, 21 orphan drugs, 558 drugs requiring data submission (including 9 incrementally modified drugs), and 13 drug substances were approved. Among the drugs requiring data submission (549 items), those with new salts or isomers had the highest ratio by 69.6% (382 items). They were followed by those with new composition (18.4%, 101 items) and those with new dosage form (same route of administration) (refer to Table 25).

Table 25. Approval status of Drugs(Chemical Drugs) by Review Type in 2022

Type	Review Type		Number of Approved Items	
1	New drugs	New drugs	20	19
2		New orphan drugs		1
3	Orphan drugs		21	
4	Drugs requiring data submission		558	
4-1	Incrementally modified drugs	New composition	9	7
		New drug therapeutic class		2
4-2	Drugs requiring data submission	New salts or isomers	549 (100%)	382(69.6%)
4-3		New therapeutic class		2(0.4%)
4-4		New composition		101(18.4%)
4-5		Change in strength		29(5.3%)
4-6		New mode of administration/dosage		3(0.5%)
4-7				
4-8		New dosage form (same route of administration)		30(5.5%)
4-9		New route of administration		2(0.4%)
5	Drug substances		13	

In 2022, the drug approval system underwent the following changes.

As the supply of active ingredients of medicines for cold had been disrupted due to the resurgence of COVID-19, a plan for applying multiple standards for some ingredients was quickly prepared to booster production and stable supply of medicines for cold. In November 2022, the subjects for the "official communication channel for medical products" pilot operation were expanded to some kinds of drugs requiring data submission, so that drugs with new composition of active ingredients and drugs with new therapeutic class can also be handled through the pathway. It is operated by applying civil service counseling results conducted in the process of medical products approval and review to the approved and reviewed contents.

In addition, for advancement and international harmonization of regulatory, a method of managing manufacturing methods based on the Common Technical Document (CTD) was introduced. In order to prevent confusion from the introduction of the system and increase the efficiency of work procedures, the "Guidelines for Management of Matters Approved Following the Adoption of Manufacturing Method based on CTD (Guidelines for Applicants)" were established to prepare detailed work procedures. The guidelines were disseminated to related associations, etc. The guidelines for applicants are available on the MFDS official website (www.mfds.go.kr) at ▶ Electronic Civil Petitions ▶ Guidelines for Industries ▶ Guidelines for Public Officials/ Guidelines for Applicants.

2.1. Approval Status of New Drugs

The number of new drugs approved in 2022 was 20 items (5 manufactured items and 15 imported items), decreased by 13% compared to 2021. The top efficacy classifications of the approved items were circulatory system drugs and drugs for blood/body fluids (5 items), chemotherapeutic agents (4 items), anti-tumor agents (3 items), nervous system drugs, respiratory sytem drugs, and anti-allergic drugs (2 items, respectively) in descending order (refer to Table 26 to Table 27).

Table 26. Approval Status of New Manufactured/Imported Drugs (2014-2022) (Chemical Drugs)

(Unit: Number of items)

	2014	2015	2016	2017	2018	2019	2020	2021	2022
Manufactured	3	6	2	1	2	4	5	4	5
Imported	38	22	22	20	9	28	29	19	15
Total	41[1)]	28[2)]	24[3)]	21[4)]	11[5)]	32[6)]	34[7)]	23[8)]	20[9)]
Year-on-Year Increase (%)	-	-31.7%	-14.3%	-12.5%	-47.6%	190.9%	6.3%	-32.4%	-13.0%

1) Includes 1 new drug with a post-approval change including revocation from the orphan drug list in 2014: (Revoked from the orphan drug list) Symbenda Inj.
2) 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
3) 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
4) 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
5) 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
6) 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

7) 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

8) 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

9) 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)

Table 27. Approval Status of New Drugs by Detailed Classification (2014-2022) (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	Anti-hormone drugs	Dermatologic drugs	Digestive system drugs	Drugs for public hygiene	Total
2014	16	1	5	0	8	0	2	5	0	2	1	1	0	0	0	0	41
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

The product names, manufacturers, dates of approval, active ingredients, efficacy and effectiveness, mechanism of action for new drugs approved in 2022 in the order of approval dates are as follows:

“Lorviqua (lorlatinib) Tablet” (Pfizer Pharmaceuticals Korea Limited, 2022.5.11., new drug with a post-approval change) is used for the treatment of adult patients with anaplastic lymphoma kinase (ALK) positive metastatic non-small cell lung cancer (NSCLC). The active ingredient **“lorlatinib”** is an anaplastic lymphoma kinase (ALK) inhibitor that thwarts the abnormal growth of ALK-mutated tumor cells.

“Vocabria Tablet 30 mg (Cabotegravir Sodium)” and **“Vocabria Injection (Cabotegravir)”** (GSK Korea, approved on 2022.2.3.) are drugs used in combination therapy with rilpivirine preparations for the treatment of HIV-1 infection. The active ingredient of this drug is **“cabotegravir”** which blocks the replication of the virus by inhibiting the enzyme (Integrase Strand Transfer Inhibitor) involved in the insertion of HIV virus DNA into human DNA.

“Epclusa Tablet” (Gilead Sciences Korea Ltd., approved on 2022.2.17.) is used in itself or in combination with ribavirin for the treatment of genotypes 1-6 chronic hepatitis C virus (HCV). The active ingredients **“sofosbuvir”** and **“velpatasvir”** inhibit 5B (NS5B) polymerase, a protein involved in HCV RNA proliferation in the cytoplasmic endoplasmic reticulum, and non-structural protein 5A (NS5A) of HCV virus, respectively, to block viral replication and hyperplasia.

“Vosevi Tablet” (Gilead Sciences Korea Ltd., approved on 2022.3.23.) is a treatment for patients with genotype 1, 2, 3, 4, 5, or 6 who were treated with HCV therapy including NS5A inhibitors and patients with genotype 1a or 3 who were treated with HCV therapy including sofosbuvir without NS5A inhibitors, among adult patients with chronic hepatitis C virus (HCV) infection

without hepatocirrhosis or with compensated hepatocirrhosis. The active ingredients **"sofosbuvir," "velpatasvir," and "voxilaprevir"** inhibits 5B (NS5B) polymerase, a protein involved in HCV RNA proliferation in the cytoplasmic endoplasmic reticulum, non-structural protein 5A (NS5A) of HCV virus, and NS3/4A proteolytic enzymes, respectively, to block viral replication and hyperplasia.

"Jyseleca 100 mg, 200 mg Film-coated Tablets (filgotinib maleate)" (Eisai Korea Inc., approved on 2022.4.1.) is used in the treatment of moderate to severe active rheumatoid arthritis in adults who response inadequately or do not have tolerability to one or more antirheumatic drugs. The active ingredient **"filgotinib maleate"** improves rheumatoid arthritis by inhibiting JAK (Janus Kinase), which is involved in signal transduction in the inflammatory response, and blocking intracellular signal transduction mediated by cytokines.

"Inrebic Capsule (fedratinib hydrochloride hydrate)" (BMS Pharmaceutical Korea Ltd., approved on 2022.4.27.) is used to treat splenomegaly or symptoms related to ▲ primary myelofibrosis ▲ myelofibrosis after polycythemia vera ▲ post-polycythaemia vera myelofibrosis in adult patients who were previously treated with ruxolitinib. The active ingredient **"fedratinib hydrochloride hydrate"** inhibits the hyperplasia of malignant tumor cells by inhibiting JAK2 (Janus Kinase) and reducing the phosphorylation of cell signaling factors and transcriptional activator proteins.

"Kerendia Tablet 10, 20 mg (finerenone)" (Bayer Korea Ltd., approved on 2022.5.10.) is effective in reducing the risk of the hospitalization due to ▲ continuous decrease in estimated glomerular filtration rate in adult patients with chronic kidney disease with type 2 diabetes, ▲ reaching end-stage renal

disease, ▲ death due to cardiovascular disease, and ▲ non-fatal myocardial infarction and heart failure. The active ingredient **“finerenone”** is a non-steroidal selective Mineral corticoid Receptor Antagonist, which attenuates inflammation and fibrosis mediated by an increase in mineralocorticoid receptors.

“REYVOW Tablet 50, 100 mg (lasmiditan hemisuccinate)” (Ildong Pharmaceutical Co., Ltd., approved on 2022.05.11.) is an acute treatment of migraine with or without aura. The active ingredient **“lasmiditan hemisuccinate”** is a selective serotonin 1F (5HT1F) receptor agonist, which exerts therapeutic effects in the treatment of migraine by reducing neuropeptide release and inhibiting pain transmission pathways including at the trigeminal nerve.

“Beova Tablet 50 mg (vibegron)” (JEIL PHARMACEUTICAL CO., LTD., approved on 2022.10.31.) is used to treat symptoms of urinary urgency, urinary frequency, and urge incontinence of overactive bladder. The active ingredient **“vibegron”** improves overactive bladder by selectively acting on $\beta 3$ adrenergic receptors to relax muscles (smooth muscles) surrounding the bladder.

“Akynzeo Injection” (HK inno.N corporation, approved on 2022.10.31.) is used to prevent acute and delayed forms of nausea and vomiting induced by initial and repeated treatment with severe or moderate chemotherapy-induced nausea and vomiting. The active ingredients of this drug, **“fosnetupitant chloride hydrochloride”** and **“palonosetron hydrochloride”** exert antiemetic prophylaxis by inhibiting the neural pathways involved in inducing nausea and vomiting.

“ENAROY Tablet 1, 2, 4 mg (enarodustat)” (JW Pharmaceutical Co., Ltd., 2022.11.17.) was developed as a treatment for symptomatic anemia in adult patients with chronic kidney disease undergoing hemodialysis. The active ingredient **“enarodustat”** is a transcription factor that regulates gene expression involved in red blood cell production, which promotes the red blood cell hematopoiesis by stabilizing HIF by inhibiting proline hydroxylase (PHD) of hypoxia inducible factor (HIF) which is degraded by HIF-proline hydroxylase.

“Envlo 0.3 mg Film-coated Tablets (Enavogliflozin)” (Daewoong Pharmaceuticals, approved on 2022.11.30.) is a treatment for diabetes through blood sugar control in patients with type 2 diabetes. The active ingredient **“enavogliflozin”** is a selective inhibitor of the sodium-glucose cotransporter 2 (SGLT2) in the renal tubule, which blocks the reabsorption of glucose excreted in the urine into the bloodstream.

“Zavicefta Injection 2 g/0.5 g (ceftazidime/avibactam)” (Pfizer Pharmaceuticals Korea Limited, approved on 2022.12.22.) is used for ▲complicated intra-abdominal infection (cIAI) ▲complicated urinary tract infection (cUTI) including pyelonephritis ▲ hospital-acquired pneumonia (HAP) including ventilator-associated pneumonia (VAP) in adult and pediatric patients aged 3 months or older. The active ingredient **“ceftazidime”** inhibits bacterial peptidoglycan cell wall synthesis, to induce bacterial lysis and cell death, and **“avibactam”** maintains antibacterial activity as a beta-lactamase inhibitor.

Table 28. New Drugs Approved in 2022 (Chemical Drugs)

No.	Manufactured /Imported	Product Name	Company	Date of Approval (Designation)	Classification	Efficacy/Effectiveness (partially omitted)
1	Imported	Lorviqua tablet 25 mg (lorlatinib)	Pfizer Pharmaceutical Korea Limited	(Revoked from the orphan drug list, switched as new drug on 2022-05-11) *Initial Approval Date: 2021-07-29	Anti-tumor agents	Treatment of adult patients with anaplastic lymphoma kinase (ALK) positive metastatic non-small cell lung cancer (NSCLC)
2	Imported	Lorviqua tablet 100 mg (lorlatinib)				
3	Imported	Vocabria tablet 30 mg (cabotegravir sodium)	GSK Korea	2022-02-03	Miscellaneous chemotherapeutic agents	Combination therapy with rilpivirine tablets for short-term treatment of HIV-1 infection in adult patients who are virologically suppressed (HIV-1 RNA < 50 copies/mL), have no history of treatment failure, and have no known or suspected resistance to cabotegravir or rilpivirine - Oral lead-in to assess tolerability of cabotegravir prior to administration of long-acting cabotegravir and rilpivirine injection - Oral therapy for patients seeking to temporarily alternate cabotegravir and rilpivirine injection therapy
4	Imported	Vocabria Injection (cabotegravir)				
5	Imported	Epclusa Tablet	Gilead Sciences Korea Ltd.	2022-02-17	Miscellaneous chemotherapeutic agents	Treatment of adults and pediatric patients aged 12 years or older and weighing 30 kg or more who were infected with genotypes 1, 2, 3, 4, 5, or 6 chronic hepatitis C virus (HCV) using this drug or in combination with ribavirin

No.	Manufactured /Imported	Product Name	Company	Date of Approval (Designation)	Classification	Efficacy/Effectiveness (partially omitted)
6	Imported	Vosevi Tablet	Gilead Sciences Korea Ltd.	2022-03-23	Miscellaneous chemotherapeutic agents	Among adult patients with chronic Hepatitis C virus (HCV) infection without hepatocirrhosis or with compensated hepato-cirrhosis (Child-Pugh A) - Treatment of patients with genotypes 1, 2, 3, 4, 5, or 6 chronic HCV infection who were treated with HCV therapy including NS5A inhibitors - Treatment of patients with genotype 1a or type 3 chronic HCV infection who were treated with HCV therapy including sofosbuvir without NS5A inhibitors
7	Imported	Jyseleca Film-coated Tablets 100 mg(filgotinib maleate)	Eisai Korea Inc.	2022-04-01	Certified therapeutic agents (including non-specific immunosuppressant)	Treatment of moderate to severe active rheumatoid arthritis in adults who do not respond adequately or have no tolerability to one or more disease-modifying anti-rheumatic drugs (DMARDs) This drug can be administered alone or in combination with methotrexate (MTX). This drug is not used with biologic disease-modifying anti-rheumatic drugs (bDMARDs) or other Janus kinase (JAK) inhibitors.
8	Imported	Jyseleca Film-coated Tablets 200 mg (filgotinib maleate)				
9	Imported	Inrebic Capsule (fedratinib hydrochloride hydrate)	BMS Pharmaceutical Korea Ltd.	2022-04-27	Anti-tumor agents	Treatment of splenomegaly or symptoms associated with the following diseases in adult patients previously treated with ruxolitinib - Primary myelofibrosis - Myelofibrosis after polycythemia vera - Myelofibrosis after essential thrombocythemia There are no data proving the efficacy of this drug in therapeutic confirmatory studies.

No.	Manufactured /Imported	Product Name	Company	Date of Approval (Designation)	Classification	Efficacy/Effectiveness (partially omitted)
10	Imported	Kerendia Tablet 10 mg (finerenone)	Bayer Korea Ltd.	2022-05-10	Miscellaneous circulatory system drugs	Reducing the risk of persistent decrease in estimated glomerular filtration rate (eGFR), reaching end-stage renal disease, death from cardiovascular disease, hospitalization due to non-fatal myocardial infarction and heart failure in patients with chronic kidney disease
11	Imported	Kerendia Tablet 20 mg (finerenone)				
12	Imported	REYVOW Tablet 50 mg (lasmiditan hemisuccinate)	ILDONG PHARMACEUTICAL CO.,LTD.	2022-05-11	Antipyretics, analgesics, and anti-inflammatory drugs	acute treatment of migraine with or without aura
13	Imported	REYVOW Tablet 100 mg (lasmiditan hemisuccinate)				
14	Imported	Akynzeo Injection	HK inno.N corporation	2022-10-31	Emetics and antiemetics	Adult 1. Prevention of acute and delayed forms of nausea and vomiting induced by initial and repeated treatment with severe anti-cancer chemo therapeutic agents-induced emesis 2. Prevention of acute and delayed forms of nausea and vomiting induced by initial and repeated treatment with moderate anti-cancer chemo therapeutic agents-induced emesis
15	Manufactured	Beova Tablet 50 mg (vibegron)	JEIL PHARMACEUTICAL CO., LTD.	2 022-10-31	Miscellaneous urogenital and anal organ drugs	Treatment of symptoms of urinary urgency, urinary frequency and urge incontinence of overactive bladder
16	Manufactured	ENAROY Tablet 4 mg (enarodustat)	JW Pharmaceutical	2022-11-17	Miscellaneous blood and body fluid drugs	Treatment of symptomatic anemia in adult patients with chronic kidney disease under-going hemodialysis
17	Manufactured	ENAROY Tablet 1 mg (enarodustat)				
18	Manufactured	ENAROY Tablet 2 mg (enarodustat)				
19	Manufactured	Envlo Film-coated Tablets 0.3 mg (enavogliflozin)	Daewoong Pharmaceuticals	2022-11-30	Antidiabetics	This drug is administered as an adjunct to diet and exercise therapy to improve blood sugar control in patients with type 2 diabetes. - Monotherapy - Combination therapy

No.	Manufactured /Imported	Product Name	Company	Date of Approval (Designation)	Classification	Efficacy/Effectiveness (partially omitted)
20	Imported	Zavicefta Injection 2 g/0.5 g (ceftazidime/avibactam)	Pfizer Pharmaceutical Korea Limited	2022-12-22	Acting mainly on gram-negative bacteria	1. Indication - Treatment of complicated intraperitoneal infection (cIAI) in adults and pediatric patients aged 3 months or older(can be used in combination with metronidazole) - Treatment of complicated urinary tract infections (cUTI) including pyelonephritis in adults and pediatric patients aged 3 months or older - Treatment of hospital-acquired pneumonia(HAP) including ventilator-associated pneu-monia(VAP) in adult patients aged 18 years or older 2. Effective for: - Complex intraperitoneal infection: Gram-negative bacteria: Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa. - Complex urinary tract infection: Gram-negative bacteria : Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterobacter cloacae, Pseudomonas aeruginosa. - Hospital-acquired pneumonia, including ventilator-associated pneumonia : Gram-negative bacteria : Enterobacter cloacae, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Serratia marcescens, Pseudomonas aeruginosa.

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

2.2. Approval Status of Orphan Drugs

The chemical drugs approved as orphan drugs in 2022 were 21 items (3 manufactured items, 18 imported items) (refer to Table 29).

Analyzing the approved orphan drugs by their therapeutic class, 16 anti-tumor agents, 2 miscellaneous respiratory drugs, 2 miscellaneous central nervous system drugs, and 1 miscellaneous chemotherapeutic agent were approved. 9 ingredients out of the 15 ingredients of orphan drugs approved in 2022 were newly designated as ingredients of orphan drugs in 2021 and the others were as follows: 7 “pirfenidone” in 2012, “edaravone” in 2015, “erdafitinib” in 2019, and “mobocertinib,” “arsenic trioxide,” and “lurbinectedin” in 2020.

Table 29. Orphan Drugs Approved in 2022 (Chemical Drugs)

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Class.	Efficacy/Effectiveness	Designation Status of Orphan Drugs	
1	Manufactured	Unifenidon Tab. 200 mg (pirfenidone)	Union Korea Pharm Co., Ltd.	2022-01-20	Miscella-neous respiratory drugs	Treatment of idiopathic pulmonary fibrosis	No.	139 (Designated in 2012)
							Ingredient	Pirfenidone
2	Manufactured	Unifenidon Tab. 400 mg (pirfenidone)					Indication	Treatment of idiopathic pulmonary fibrosis
3	Imported	Lumakras Tab. 120 mg (sotorasib)	AMGEN KOREA	2022-02-14	Anti-tumor agents	Treatment of adult patients with KRAS G12C mutation locally advanced or metastatic non-small cell lung cancer (NSCLC) who previously received treatment at least once	No.	291 (Designated in 2021)
							Ingredient	Sotorasib
							Indication	KRAS p. G12C mutation locally advanced and metastatic non-small cell lung cancer who received one or more treatments
4	Imported	Brukinsa Capsules 80 mg (zanubrutinib)	BeiGene Korea	2022-02-24	Anti-tumor agents	Mantle cell lymphoma (MCL) Monotherapy in adult patients with mantle cell lymphoma (MCL) who previously received treatment at least once Waldenström macroglobulinemia (WM) Monotherapy in adult patients with aldenström macroglobulinemia (WM) who previously received treatment at least once	No.	274 (Designated in 2021)
							Ingredient	Zanubrutinib
							Indication	1. Mantle cell lymphoma which received one or more treatments 2. Treatment of previously treated patients with Waldenström macroglobulinemia (WM) 3. Relapsed/refractory marginal zone lymphoma (R/R MZL) with one or

								more prior treatments
5	Imported	Retevmo Capsules 40 mg (selpercatinib)	Lily Korea	2022-03-11	Anti-tumor agents	1. Metastatic Rearranged during Transfection (RET) fusion-positive non-small cell lung carcinoma This drug is used for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung carcinoma (NSCLC) The efficacy and effectiveness of this drug were approved based on the overall response rate, and there is no clinical study result that demonstrates clinical benefits such as an increase in the duration of survival 2. Advanced or metastatic RET-mutant medullary thyroid carcinoma requiring systemic therapy This drug is used for the treatment of adult and pediatric patients aged 12 years or older with advanced or metastatic RET-mutation medullary thyroid carcinoma (MTC) requiring systemic therapy. The efficacy and effectiveness of this drug were approved based on the overall response rate, and there is no clinical study result that demonstrates clinical benefits such as an increase in the duration of survival. 3. RET fusion-positive thyroid cancer requiring systemic therapy with prior sorafenib and/or lenvatinib treatment experience This drug is used for the treatment of adult patients with advanced or metastatic RET fusion-positive radioiodine relapsed thyroid cancer, previously treated with sorafenib and/or lenvatinib, and requiring systemic therapy. The efficacy and effective-ness of this drug were approved based on the overall response rate, and there is no clinical study result that demonstrates clinical benefits such as an increase in the duration of survival.	No.	287 (Designated in 2021)
							Ingredient	Selpercatinib
6	Imported	Retevmo Capsules 80 mg (selpercatinib)					Indication	1. Metastatic REarranged during Transfection (RET) fusion-positive non-small cell lung carcinoma 2. Advanced or metastatic RET-mutant medullary thyroid carcinoma requiring systemic therapy 3. Advanced or metastatic RET fusion-positive thyroid cancer requiring systemic therapy, with radioiodine refractory

7	Imported	ONUREG (azacitidine) tablets 200 mg	BMS Pharmaceutical Korea Ltd.	2022-03-23	Anti-tumor agents	Maintenance therapy in adult patients with acute myeloid leukemia who achieved complete remission (CR) or complete remission with incomplete hematologic recovery(CRi) after induction therapy, irrespective of receiving consolidation therapy, and unsuitable for hematopoietic stem cell transplantation (HSCT) therapy	No.	296 (Designated in 2021)
							Ingredient	Azacitidine
8	Imported	ONUREG (azacitidine) tablets 300 mg					Indication	Maintenance therapy in adult patients with acute myeloid leukemia who achieved complete remission (CR) or complete remission with incomplete hematologic recovery (CRi) after induction therapy ,irrespective of receiving consolidation therapy, and unsuitable for hematopoietic stem cell transplantation (HSCT) therapy
9	Imported	Gavreto Capsule 100 mg (Pralsetinib)	Roche Korea	2022-03-29	Anti-tumor agents	1. Treatment of adult patients with REarranged during Transfection (RET) fusion-positive locally advanced or metastatic non-small cell lung carcinoma The efficacy of this drug was based on response rate and response duration, and there are no data demonstrating improvement in the duration of survival. 2. Treatment of adult patients with RET-mutant locally advanced or metastatic medullary thyroid carcinoma requiring systemic therapy The efficacy of this drug was based on response rate and response duration, and there are no data demonstrating improvement in the duration of survival.	No.	293 (Designated in 2021)
							Ingredient	Pralsetinib
							Indication	1. Locally advanced or metastatic Rearranged during Transfection (RET) fusion-positive non-small cell lung carcinoma 2. Locally advanced or metastatic RET-mutant medullary thyroid carcinoma requiring systemic therapy 3. Locally advanced or metastatic RET fusion-positive radioiodine refractory thyroid cancer requiring systemic therapy
10	Manufactured	Fra-Cut Injection (edaravone)	BUKWANG PHARM CO., LTD.	2022-05-13	Miscellaneous central nervous system drugs	Slows the progression of dysfunction caused by amyotrophic lateral sclerosis (ALS).	No.	190 (Designated in 2015)
							Ingredient	Edaravone
							Indication	Amyotrophic lateral sclerosis (ALS)
11	Imported	Scemblix Tablets 20 mg (asciminib hydrochloride)	Novartis Pharma Korea ltd.	2022-06-09	Anti-tumor agents	Treatment of adult patients with chronic Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in the chronic phase previously treated with two or more tyrosine kinase inhibitors (TKI) The efficacy of this drug is based on major molecular response rates and cytogenetic response rates.	No.	295 (Designated in 2021)
							Ingredient	Asciminib
12	Imported	Scemblix Tablets 40 mg (asciminib hydrochloride)					Indication	Treatment of adult patients with chronic Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) in the chronic phase previously treated with two or more tyrosine kinase inhibitors
13	Imported	Exkivity Capsule 40 mg (mobocertinib succinate)	Takeda Pharmaceuticals Korea Co., Ltd.	2022-07-19	Anti-tumor agents	Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC)	No.	272 (Designated in 2020)
							Ingredient	Mobocertinib
							Indication	Treatment in patients

						with an epidermal growth factor receptor (EGFR) exon 20 insertion mutation, who have been treated previously with a platinum-based chemotherapy The efficacy of this drug was based on response rate and response duration, and there are no data demonstrating improvement in the duration of survival.		with non-small cell lung carcinoma (NSCLC) with an epidermal growth factor receptor (EGFR) exon 20 insertion mutation, who have been treated previously with a platinum-based chemotherapy
14	Imported	Asadin Injection (arsenic trioxide)	MEDITIP	2022-09-14	Anti-tumor agents	Remission induction and consolidation therapy for adult patients with refractory or relapsed acute promyelocytic leukemia Use it for patients diagnosed with acute promyelocytic leukemia by chromosome test [t(15;17) translocation] and/or genetic test [Pro-Myelo cytic Leukaemia/ Retinoic -Acid - Receptor-alpha (PML/ RAR-alpha) gene]. Prior treatment should include retinoid and chemotherapy. The efficacy and safety of this drug have not been established for acute promyelocytic leukemia that relapsed after complete remission with this drug. Response rates for other acute myeloid leukemia (AML) subtypes have not been investigated.	No.	117 (Designated in 2020)
							Ingredient	Arsenic trioxide
							Indication	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
15	Imported	Zepzelca Injection (lurbinectedin)	Boryung Co., Ltd.	2022-09-22	Anti-tumor agents	Metastatic small cell lung cancer in which first-line platinum-based chemotherapy was failed The efficacy and effectiveness of this drug was based on response rate and response duration, and there are no data demonstrating the duration of survival.	No.	278 (Designated in 2020)
							Ingredient	Lurbinectedin
							Indication	Treatment of adult patients with advanced metastatic small cell lung cancer in which first-line platinum-cntaining chemotherapy was failed
16	Imported	Ponvory Tablet (ponesimod)	Janssen Korea Ltd.	2022-10-11	Miscellaneous central nervous system drugs	Treatment of relapsing remitting multiple sclerosis in adults	No.	305 (Designated in 2021)
							Ingredient	Ponesimod
							Indication	Treatment of adult patients with relapsing multiple sclerosis

17	Imported	Balversa Tablet 3 mg (erdafitinib)	Janssen Korea Ltd.	2022-11-24	Anti-tumor agents	Treatment of patients with locally advanced or metastatic urothelial cancer with FGFR2 or FGFR3 mutation, showing disease progression during or after treatment with at least one chemotherapeutic agent including platinum-based chemotherapeutic agents, or patients with disease progression within 12 months of neoadjuvant therapy before operation or adjuvant therapy after operation, including platinum-based chemotherapeutic agents The effectiveness of this drug was based on response rate and response duration, and there are no data demonstrating improvement in the duration of survival in a therapeutic confirmatory study.	No.	254 (Designated in 2019)
							Ingredient	Erdafitinib
18	Imported	Balversa Tablet 4 mg (erdafitinib)					Indication	Treatment of patients with disease progression during or after treatment with at least one chemotherapeutic agent as adult patients with locally advanced or metastatic urothelial cancer with FGFR mutation, or patients with disease progression within 12 months of neoadjuvant therapy before operation or adjuvant therapy after operation
19	Imported	Balversa Tablet 5 mg (erdafitinib)						
20	Imported	Vyxeos Liposomal Injection	Handok Inc.	2022-11-30	Anti-tumor agents	1) Treatment of newly diagnosed therapy related acute myeloid leukemia (t-AML) in adults 2) Treatment of newly diagnosed acute myeloid leukemia with myelodysplasia -related changes (AML-MRC) in adults	No.	300 (Designated in 2021)
							Ingredient	CPX-351(liposomes containing cytarabine and daunorubicin)
							Indication	1. Treatment of newly diagnosed therapy-related acute myeloid leukemia (t-AML) in adults 2. Treatment of newly diagnosed acute myeloid leukemia with myelodysplasia -related changes (AML-MRC) in adults
21	Imported	LIVTENCITY 200 mg (maribavir)	Takeda Pharmaceuticals Korea Co., Ltd.	2022-12-27	Miscellaneous chemotherapeutic agents	Treatment of post-transplant cytomegalovirus (CMV) infection and disease in adult patients who are resistant or refractory to one or more of ganciclovir, valganci-clovir, foscarnet, or cidofovir	No.	303 (Designated in 2021)
							Ingredient	Maribavir
							Indication	Treatment of post-transplant cytomegalovirus (CMV) infection and disease in adult patients who are resistant or refractory to one or more of ganciclovir, valganciclovir, foscarnet, or cidofovir

※ Detailed approval information (efficacy/effectiveness, dosage/mode of administration, 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 usability (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 mode of 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 usability were approved, totaling to approval of 13 designated incrementally modified drugs. In 2020, 5 items with improved usability, including 4 sustained-release tablet items with improved intake convenience and compliance by a change in dosage form and mode of administration and dosage and 1 item with improved efficacy were approved as incrementally modified drugs. In 2021, 3 new combination drugs with new compositions of active ingredients and 4 items with improved usability through change in the route of administration with new dosage forms were designated as incrementally modified drugs. In 2022, 9 items, 7 items including combination drugs with improved compliance through new compositions of active ingredients and 2 items with improved efficacy through demonstrating new efficacy , were designated as incrementally modified drugs (refer to Table 30).

Table 30. Type of Incrementally Modified Drugs in 2016-2022

Year	New Drug Therapeutic Class	New Composition or Compounding Ratio	New Dosage Form (Same Route of Administration)	New Route of Administration	Total
2016	0	22	1	1	24
2017	0	7	4	0	11
2018	0	0	6	0	6
2019	0	13	0	0	13
2020	0	2	4	0	6
2021	0	3	0	4	7
2022	2	7	0	0	9

The Ministry of Food and Drug Safety has been publishing the 「Casebook of approved incrementally modified drugs」 (Guidance for applicants) since November 2011. The casebook contains the current status and cases of incrementally modified drugs for the domestic pharmaceutical industries to utilize in drug research and development. The status of incrementally modified drugs approved in 2022 will be reflected in the 「Casebook of approved incrementally modified drugs」 (Guidance for applicants) for 2023, including the approval status, product type-specific status, detailed designation criteria by case, non-designated cases, etc.

Analyzing the incrementally modified drugs by their designation criteria, drug with improved efficacy with a proven increase in therapeutic effects (68 items, 50.7%) and those with improved usability through improvement of formulation (55 items, 41.0%) accounted for 91.7% of the total incrementally modified drugs, and those with designation of advancement of pharmaceutical technology and those with improved safety accounted for 5.2% (7 items) and 3.0% (4 items) respectively (Figure 7).

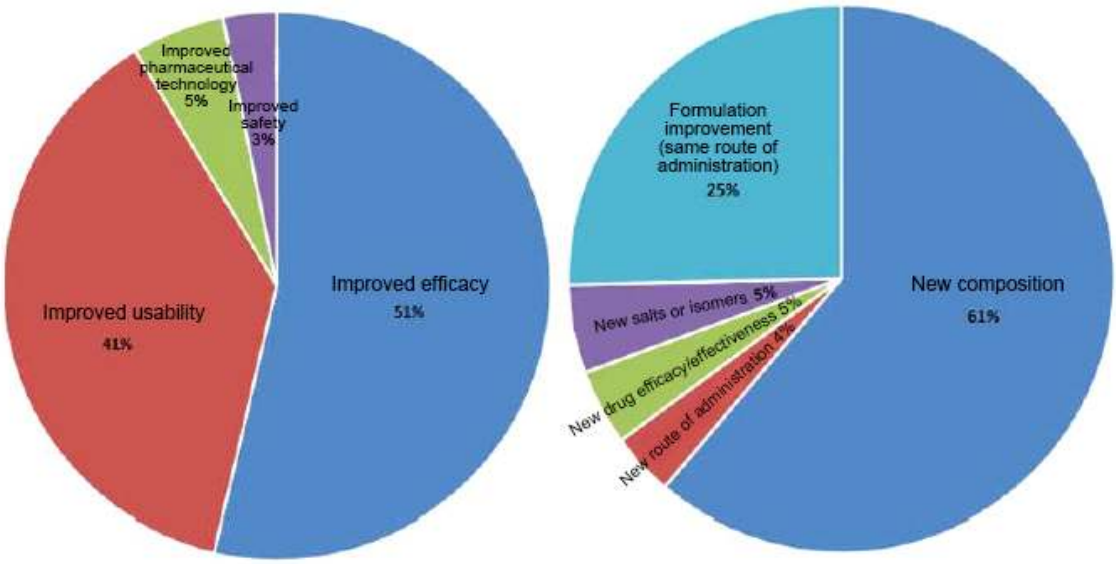

Figure 7. Approval Status of Incrementally Modified Drugs by Designation Criteria and Type (2009-2022)

Table 31. List of Incrementally Modified Drugs (2009-2022)

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		

No.	Product name	Company	Approval date	Detailed classification	Remarks
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)
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.			

No.	Product name	Company	Approval date	Detailed classification	Remarks
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
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				

No.	Product name	Company	Approval date	Detailed classification	Remarks
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				
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

No.	Product name	Company	Approval date	Detailed classification	Remarks
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
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

No.	Product name	Company	Approval date	Detailed classification	Remarks
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
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	Antiarterioscler-otic agents	Change in the type of active substance or compounding ratio
120	LivaloZet Tablet 2/ 10mg	JW Pharmaceutical	2021-07-28	Antiarterioscler-otic 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	Change in dosage form, strength and mode of administration/dosage
123	Donerion Patch 175mg (Donepezil)				

No.	Product name	Company	Approval date	Detailed classification	Remarks
124	Donhesive Patch 87.5mg (Donepezil)	ICURE Pharmaceutical Inc.	2021-11-05	Miscellaneous central nervous system drugs	Change in dosage form, strength and mode of administration/dosage
125	Donhesive Patch 175mg (Donepezil)				
126	Dukarb Plus Tab. 30/5/12.5 mg	Boryung Co., Ltd.	2022-03-31	Anti-hypertensives	Change of active substance type or compounding ratio
127	Dukarb Plus Tab. 0/10/12.5 mg	Boryung Co., Ltd.	2022-03-31	Anti-hypertensives	Change of active substance type or compounding ratio
128	Dukarb Plus Tab. 60/10/25 mg	Boryung Co., Ltd.	2022-03-31	Anti-hypertensives	Change of active substance type or compounding ratio
129	Dukarb Plus Tab. 60/5/12.5 mg	Boryung Co., Ltd.	2022-03-31	Anti-hypertensives	Change of active substance type or compounding ratio
130	Dukarb Plus Tab. 60/5/25 mg	Boryung Co., Ltd.	2022-06-10	Anti-hypertensives	Change of active substance type or compounding ratio
131	REBAEYE 2%(rebamipide)	Kukje Pharm.	2022-06-16	Ophthalmic drugs	Change of efficacy/effectiveness
132	RevaK Eyedrops (rebamipide)	Sam Il	2022-06-16	Ophthalmic drugs	Change of efficacy/effectiveness
133	Zemidapa Tablet	LG Chem	2022-06-21	Antidiabetics	Change of active substance type or compounding ratio
134	AFEXON Tab.	Aju Pharm	2022-09-14	Antipyretics, analgesics, and anti-inflammatory drugs	Change of active substance type 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 efficacy groups, ▲New composition of active substances, or changes only in strength, ▲Drugs with new administration routes, ▲Drugs with new administration/ dosage, ▲New dosage form (same administration route), etc.

Among the drugs requiring data submission (excluding 9 incrementally modified drug items) approved in 2022, the development of drugs with a new salts or isomers accounted for the largest portion (69.6%, 382 items), followed by drugs with new composition or changes in strength (23.7%, 130 items) (refer to Table 32).

Table 32. Drugs Requiring Data Submission Approved in 2022

Review Type of Drugs Requiring Data Submission		Number of Approved Items	
New salts or isomers		382 (69.6%)	
New therapeutic class		2 (0.4%)	
New composition of active substance or change only in strength	130 (23.7%)	New composition	101 (18.4%)
		Change in strength	29 (5.3%)
New route of administration		2 (0.4%)	
New mode of administration/dosage		3 (0.5%)	
New dosage form (same route of administration)		30 (5.5%)	
Total		549	

※ Excluding incrementally modified drugs (drugs requiring data submission)

2.4.1. New Salt or Isomer Drugs

382 manufactured chemical drugs were approved with new salts or isomers, including 201 items (52.6%) developed from sitagliptin phosphate hydrate, a previously approved anti-diabetics, into sitagliptin hydrochloride, 115 items (30.1%) developed from teneligliptin hydrobromide hydrate as a new salt (citric acid, formate, and L-proline), 34 items (8.9%) developed from dapagliflozin propanediol hydrate as a new salt (citric acid, formate, L-proline), and 15 items (3.9%) of combination drugs developed from sitagliptin phosphate hydrate and dapagliflozin propanediol hydrate as new salts. As a result, the anti-diabetics accounted for the majority of the new salt or isomer drugs approved in 2022.

Other approved drugs include: 9 items developed from antihistamine bepotastine salicylate into bepotastine besylate, 4 items developed from an anticoagulant edoxaban tosylate hydrate into edoxaban besylate hydrate, an antihypertensive drug amlodipine besylate developed with new salts in 2 items, 1 item in which tenofovir alafenamide hemi-fumarate, a drug for liver disease, was changed to tenofovir alafenamide citrate, and 1 item developed from an inorganic preparation ferric hydroxide sucrose complex into ferric pyrophosphate citrate sodium sulfate co-precipitate hydrate (refer to Table 33).

Table 33. Drugs Requiring Data Submission with New Salt or New Isomer Approved in 2022

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
1	Manufactured	Siglip Duo Tab. 50/1000 mg	Edenpahrma	2022-01-03	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
2	Manufactured	Siglip Duo Tab. 50/500 mg	Edenpahrma	2022-01-03	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
3	Manufactured	Siglip Duo Tab. 50/850 mg	Edenpahrma	2022-01-03	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
4	Manufactured	Citaren Duo Tab. 50/1000 mg	Nexpharm Korea	2022-01-03	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
5	Manufactured	Citaren Duo Tab. 50/500 mg	Nexpharm Korea	2022-01-03	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
6	Manufactured	Citaren Duo Tab. 50/850 mg	Nexpharm Korea	2022-01-03	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
7	Manufactured	Nexgliptinduo Tab. 50/1000 mg	Binex	2022-01-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
8	Manufactured	Nexgliptinduo Tab. 50/500 mg	Binex	2022-01-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
9	Manufactured	Nexgliptinduo Tab. 50/850 mg	Binex	2022-01-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
10	Manufactured	SitaforminAlpha Tab. 50/1000 mg	Daehan New Pharm	2022-01-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
11	Manufactured	SitaforminAlpha Tab. 50/500 mg	Daehan New Pharm	2022-01-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
12	Manufactured	SitaforminAlpha Tab. 50/850 mg	Daehan New Pharm	2022-01-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
13	Manufactured	Janusitinm Tablet 50/1000 mg	Pharvis Korea Co., Ltd.	2022-01-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
14	Manufactured	Janusitinm Tablet 50/500 mg	Pharvis Korea Co., Ltd.	2022-01-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
15	Manufactured	Janusitinm Tablet 50/850 mg	Pharvis Korea Co., Ltd.	2022-01-06	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
16	Manufactured	Sitamefo Tab 50/1000 mg	Youngil Pharm	2022-01-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
17	Manufactured	Sitamefo Tab 50/500 mg	Youngil Pharm	2022-01-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
18	Manufactured	Sitamefo Tab 50/850 mg	Youngil Pharm	2022-01-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
19	Manufactured	A-sitamet Tab. 50/1000 mg	Ahn-Gook Pharmaceutical	2022-01-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
20	Manufactured	A-sitamet Tab. 50/500 mg	Ahn-Gook Pharmaceutical	2022-01-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
21	Manufactured	A-sitamet Tab. 50/850 mg	Ahn-Gook Pharmaceutical	2022-01-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
22	Manufactured	Sitava-M tablet 50/1000 mg	Aprogen Biologics Inc.	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
23	Manufactured	Sitava-M tablet 50/500 mg	Aprogen Biologics Inc.	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
24	Manufactured	Sitava-M tablet 50/850 mg	Aprogen Biologics Inc.	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
25	Manufactured	JANUGLIPTINMET TAB. 50/500 mg	Young Poong Pharm.	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
26	Manufactured	JANUGLIPTINMET TAB. 50/850 mg	Young Poong Pharm.	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
27	Manufactured	JANUDAUM-M TAB. 50/1000 MG	Daewoong Bio	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
28	Manufactured	JANUDAUM-M TAB. 50/500 MG	Daewoong Bio	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
29	Manufactured	JANUDAUM-M TAB. 50/850 MG	Daewoong Bio	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
30	Manufactured	Kwangdong Meposita tab. 50/1000 mg	Kwang Dong Pharm.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
31	Manufactured	Kwangdong Meposita tab. 50/500 mg	Kwang Dong Pharm.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
32	Manufactured	Kwangdong Meposita tab. 50/850 mg	Kwang Dong Pharm.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
33	Manufactured	Celltamet Tablet 50/1000 mg	Celltrion Pharm, Inc.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
34	Manufactured	Celltamet Tablet 50/500 mg	Celltrion Pharm, Inc.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
35	Manufactured	Celltamet Tablet 50/850 mg	Celltrion Pharm, Inc.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
36	Manufactured	SigliptinM Tab. 50/1000 mg	MEDICA KOREA Co., Ltd.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
37	Manufactured	SigliptinM Tab. 50/500 mg	MEDICA KOREA Co., Ltd.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
38	Manufactured	SigliptinM Tab. 50/850 mg	MEDICA KOREA Co., Ltd.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
39	Manufactured	Sitaro-M tab. 50/1000 mg	Hanlim Pharm. Co., Ltd.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
40	Manufactured	Sitaro-M tab. 50/500 mg	Hanlim Pharm. Co., Ltd.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
41	Manufactured	Sitaro-M tab. 50/850 mg	Hanlim Pharm. Co., Ltd.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
42	Manufactured	S Met 50/1000 mg Tab.	Boryung Co., Ltd. Biopharma Co., Ltd.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
43	Manufactured	S Met 50/500 mg Tab.	Boryung Co., Ltd. Biopharma Co., Ltd.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
44	Manufactured	S Met 50/850 mg Tab.	Boryung Co., Ltd. Biopharma Co., Ltd.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
45	Manufactured	Januarin-duo Tab. 50/1000 mg	IL-YANG PHARM.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
46	Manufactured	Januarin-duo Tab. 50/500 mg	IL-YANG PHARM.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
47	Manufactured	Januarin-duo Tab. 50/850 mg	IL-YANG PHARM.	2022-01-19	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
48	Manufactured	Triferic Solution (ferric pyrophosphate citrate sodium sulfate coprecipitate hydrate)	JEIL PHARMACEUTICAL CO., LTD.	2022-01-19	Mineral preparations	Ferric hydroxide sucrose complex → Ferric pyrophosphate citrate sodium sulfate co-precipitate hydrate
49	Manufactured	Esliptin-M Tab. 50/500 mg	WITHUS PHARMACEUTICAL CO., LTD.	2022-01-20	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
50	Manufactured	Esliptin-M Tab. 50/850 mg	WITHUS PHARMACEUTICAL CO., LTD.	2022-01-20	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
51	Manufactured	DANG E JANU COMBI TAB 50/1000 mg	Myungmoon Pharm.	2022-01-24	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
52	Manufactured	DANG E JANU COMBI TAB 50/500 mg	Myungmoon Pharm.	2022-01-24	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
53	Manufactured	DANG E JANU COMBI TAB 50/850 mg	Myungmoon Pharm.	2022-01-24	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
54	Manufactured	Sitauniduo Tab. 50/1000 mg	Union Korea Pharm Co., Ltd.	2022-01-25	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
55	Manufactured	Sitauniduo Tab. 50/500 mg	Union Korea Pharm Co., Ltd.	2022-01-25	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
56	Manufactured	Sitauniduo Tab. 50/850 mg	Union Korea Pharm Co., Ltd.	2022-01-25	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
57	Manufactured	Fosita Tab. 10/100 mg	GENUONE Sciences Inc.	2022-01-25	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
58	Manufactured	Gluforvi 10/100 mg Tab.	HANALL BIOPHARMA CO., LTD.	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
59	Manufactured	Danaliptin Plus Tab. 50/1000 mg	Danagen	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
60	Manufactured	Danaliptin Plus Tab. 50/500 mg	Danagen	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
61	Manufactured	Danaliptin Plus Tab. 50/850 mg	Danagen	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
62	Manufactured	Dapagliptin Tab. 10/100 mg	ILsung pharmaceuticals Co., Ltd.	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
63	Manufactured	DAPARO S tab. 10/100 mg	Hanlim Pharm. Co., Ltd.	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
64	Manufactured	Duogli Tab.	Daehan New Pharm	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
65	Manufactured	Dsplus Tab 10/100 mg	Yuyu pharma	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
66	Manufactured	Litesidamet Tab. 50/1000 mg	LitePharmTech Co., Ltd.	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
67	Manufactured	Litesidamet Tab. 50/500 mg	LitePharmTech Co., Ltd.	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
68	Manufactured	Litesidamet Tab. 50/850 mg	LitePharmTech Co., Ltd.	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
69	Manufactured	Sugamax Tab.10/100 mg	SAEHAN PHARM	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
70	Manufactured	Sita Forgli Tab. 10/100 mg	Korea Prime Pharm.	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
71	Manufactured	Esliptin-D Tab. 10/100 mg	WITHUS PHARMACEUTICAL CO., LTD.	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
72	Manufactured	JANUFLO TAB 10/100 MG	Daewoong Bio	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
73	Manufactured	Pasicombi Tablet 10/100 mg	Pharvis Korea Co., Ltd.	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
74	Manufactured	Ponubia Tab. 10/100 mg	CHO-DANG Pharm Co., Ltd.	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
75	Manufactured	FOSIGLIP M TAB. 10/100 mg	MOTHER'S PHARMACEUTICAL	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
76	Manufactured	Forxicombi Tab. 10/100 mg	Youngil Pharm	2022-01-28	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
77	Manufactured	Sitakanmet Tablet 50/1000 mg	Dongkook Pharmaceutical	2022-02-08	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
78	Manufactured	Sitakanmet Tablet 50/500 mg	Dongkook Pharmaceutical	2022-02-08	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
79	Manufactured	Sitakanmet Tablet 50/850 mg	Dongkook Pharmaceutical	2022-02-08	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
80	Manufactured	Anymet Tab. 50/1000 mg	GUJU Pharm Co., Ltd.	2022-02-08	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
81	Manufactured	Anymet Tab. 50/500 mg	GUJU Pharm Co., Ltd.	2022-02-08	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
82	Manufactured	Anymet Tab. 50/850 mg	GUJU Pharm Co., Ltd.	2022-02-08	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
83	Manufactured	WhanIn Sitagliptin Metformin Tab. 50/1000 mg	Whan In Pharm.	2022-02-08	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
84	Manufactured	WhanIn Sitagliptin Metformin Tab. 50/500 mg	Whan In Pharm.	2022-02-08	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
85	Manufactured	WhanIn Sitagliptin Metformin Tab. 50/850 mg	Whan In Pharm.	2022-02-08	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
86	Manufactured	Sitaglenduo Tab. 50/1000 mg	Neo Bio Korea Pharm. Co., Ltd.	2022-03-02	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
87	Manufactured	Sitaglenduo Tab. 50/500 mg	Neo Bio Korea Pharm. Co., Ltd.	2022-03-02	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
88	Manufactured	Sitaglenduo Tab. 50/850 mg	Neo Bio Korea Pharm. Co., Ltd.	2022-03-02	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
89	Manufactured	Esliptin-M Tab. 50/1000 mg	WITHUS PHARMACEUTICAL CO., LTD.	2022-03-02	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
90	Manufactured	JANUGREEN DUO TAB. 50/1000 mg	JINYANG PHARM CO., LTD.	2022-03-02	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
91	Manufactured	JANUGREEN DUO TAB. 50/500 mg	JINYANG PHARM CO., LTD.	2022-03-02	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
92	Manufactured	JANUGREEN DUO TAB. 50/850 mg	JINYANG PHARM CO., LTD.	2022-03-02	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
93	Manufactured	JANUGLIPTINMET TAB. 50/1000 mg	Young Poong Pharm.	2022-03-02	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
94	Manufactured	Teneglip M SR Tab.10/500 mg	MOTHER'S PHARMACEUTICAL	2022-03-29	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
95	Manufactured	Teneglip M SR Tab.10/750 mg	MOTHER'S PHARMACEUTICAL	2022-03-29	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
96	Manufactured	Teneglip M SR Tab.20/1000 mg	MOTHER'S PHARMACEUTICAL	2022-03-29	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
97	Manufactured	Tenegle M SR Tab. 10/500 mg	HANPOONG PHARM. Co., Ltd.	2022-04-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
98	Manufactured	Tenegle M SR Tab. 10/750 mg	HANPOONG PHARM. Co., Ltd.	2022-04-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
99	Manufactured	Tenegle M SR Tab. 20/1000 mg	HANPOONG PHARM. Co., Ltd.	2022-04-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
100	Manufactured	Danelia M SR Tab. 10/500 mg	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
101	Manufactured	Danelia M SR Tab.10/750 mg	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
102	Manufactured	Danelia M SR Tab.20/1000 mg	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
103	Manufactured	Defoteli M SR Tab 10/500 mg (teneligliptin hydrochloride hydrate, metformin hydrochloride)	REYON PHARMACEUTI-CAL CO., LTD	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
104	Manufactured	Defoteli M SR Tab 10/750 mg (teneligliptin hydrochloride hydrate, metformin hydrochloride)	REYON PHARMACEUTI-CAL CO., LTD	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
105	Manufactured	Defoteli M SR Tab 20/1000 mg (teneligliptin hydrochloride hydrate, metformin hydrochloride)	REYON PHARMACEUTI-CAL CO., LTD	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
106	Manufactured	Yootene M SR Tab. 10/500 mg	YooYoung Pharmaceutical Co., Ltd	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
107	Manufactured	Yootene M SR Tab. 10/750 mg	YooYoung Pharmaceutical Co., Ltd	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
108	Manufactured	Yootene M SR Tab. 20/1000 mg	YooYoung Pharmaceutical Co., Ltd	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
109	Manufactured	Tegly M SR tab. 10/500 mg	Sinil Pharm	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
110	Manufactured	Tegly M SR tab. 10/750 mg	Sinil Pharm	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
111	Manufactured	Tegly M SR tab. 20/1000 mg	Sinil Pharm	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
112	Manufactured	TENEGREEN DUO SR TAB. 10/500 mg	JINYANG PHARM CO., LTD.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
113	Manufactured	TENEGREEN DUO SR TAB. 10/750 mg	JINYANG PHARM CO., LTD.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
114	Manufactured	TENEGREEN DUO SR TAB. 20/1000 mg	JINYANG PHARM CO., LTD.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
115	Manufactured	Teneglitin M SR Tab.10/500 mg	Pharvis Korea Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
116	Manufactured	Teneglitin M SR Tab. 10/750 mg	Pharvis Korea Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
117	Manufactured	Teneglitin M SR Tab. 20/1000 mg	Pharvis Korea Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
118	Manufactured	Tenero M SR Tab. 10/500 mg	Hanlim Pharm. Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
119	Manufactured	Tenero M SR Tab. 10/750 mg	Hanlim Pharm. Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
120	Manufactured	Tenero M SR tab. 20/1000 mg	Hanlim Pharm. Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
121	Manufactured	Teneliptin-M SR Tablet 10/500 mg	HLB Pharmaceutical Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
122	Manufactured	Teneliptin-M SR Tablet 10/750 mg	HLB Pharmaceutical Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
123	Manufactured	Teneliptin-M SR Tablet 20/1000 mg	HLB Pharmaceutical Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
124	Manufactured	TENESE M SR tab. 10/500 mg	AJU PHARM CO., LTD.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
125	Manufactured	TENESE M SR tab. 10/750 mg	AJU PHARM CO., LTD.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
126	Manufactured	TENESE M SR tab. 20/1000 mg	AJU PHARM CO., LTD.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
127	Manufactured	TENETIN M SR 100/500 mg	Daewon Pharm.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
128	Manufactured	TENETIN M SR 10/750 mg	Daewon Pharm.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
129	Manufactured	TENETIN M SR 20/1000 mg	Daewon Pharm.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
130	Manufactured	TENELDI-M 10/500 mg	Kukje Pharm.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
131	Manufactured	TENELDI-M 10/750 mg	Kukje Pharm.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
132	Manufactured	TENELDI-M 20/1000 mg	Kukje Pharm.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
133	Manufactured	Tenela M SR tab. 10/500 mg (teneligliptin hydrochloride hydrate, metformin hydrochloride)	DalimBioTech Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
134	Manufactured	Tenela M SR tab. 10/750 mg (teneligliptin hydrochloride hydrate, metformin hydrochloride)	DalimBioTech Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
135	Manufactured	Tenela M SR tab. 20/1000 mg (teneligliptin hydrochloride hydrate, metformin hydrochloride)	DalimBioTech Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
136	Manufactured	Tenell-M SR Tab. 10/500 mg	MEDICA KOREA Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
137	Manufactured	Tenell-M SR Tab. 10/750 mg	MEDICA KOREA Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
138	Manufactured	Tenell-M SR Tab. 20/1000 mg	MEDICA KOREA Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
139	Manufactured	Tenelformin SR Tab. 10/500 mg	Daehan New Pharm	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
140	Manufactured	Tenelformin SR Tab. 10/750 mg	Daehan New Pharm	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
141	Manufactured	Tenelformin SR Tab. 20/1000 mg	Daehan New Pharm	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
142	Manufactured	Tediem Met XR Tab. 10/500 mg	Dongwha Pharm. Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
143	Manufactured	Tediem Met XR Tab. 10/750 mg	Dongwha Pharm. Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
144	Manufactured	Tediem Met XR Tab. 20/1000 mg	Dongwha Pharm. Co., Ltd.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
145	Manufactured	TERALIPTIN DUO SR Tab. 10/500 mg	PharmGen Science, Inc.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
146	Manufactured	TERALIPTIN DUO SR Tab. 10/750 mg	PharmGen Science, Inc.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
147	Manufactured	TERALIPTIN DUO SR Tab. 20/1000 mg	PharmGen Science, Inc.	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
148	Manufactured	Telia M SR Tab. 10/500 mg	Sam Chun Dang Pharm	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
149	Manufactured	Telia M SR Tab. 10/750 mg	Sam Chun Dang Pharm	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
150	Manufactured	Telia M SR Tab. 20/1000 mg	Sam Chun Dang Pharm	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
151	Manufactured	Tineglip M SR Tab. 10/500 mg	Binex	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
152	Manufactured	Tineglip M SR Tab. 10/750 mg	Binex	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
153	Manufactured	Tineglip M SR Tab. 20/1000 mg	Binex	2022-04-04	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
154	Manufactured	Teneron M SR Tab 10/500 mg	Korea Prime Pharm.	2022-04-06	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
155	Manufactured	Teneron M SR Tab 10/750 mg	Korea Prime Pharm.	2022-04-06	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
156	Manufactured	Teneron M SR Tab. 20/1000 mg	Korea Prime Pharm.	2022-04-06	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
157	Manufactured	TenerinM SR Tab 10/500 mg	Nexpharm Korea	2022-04-08	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
158	Manufactured	TenerinM SR Tab 10/750 mg	Nexpharm Korea	2022-04-08	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
159	Manufactured	TenerinM SR Tab 20/1000 mg	Nexpharm Korea	2022-04-08	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
160	Manufactured	Tedi 4M XR tab. 10/500 mg	Dongkwang Pharm.	2022-04-08	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
161	Manufactured	Tedi 4M XR tab. 10/750 mg	Dongkwang Pharm.	2022-04-08	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
162	Manufactured	Tedi 4M XR tab. 20/1000 mg	Dongkwang Pharm.	2022-04-08	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
163	Manufactured	Teriggle Tab. 20 mg (teneligliptin ditosylate dihydrate)	SHIN POONG PHARM. CO., LTD	2022-04-27	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
164	Manufactured	NanumetXR Tab. 10/1000 mg	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
165	Manufactured	NanumetXR Tab. 50/1000 mg	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
166	Manufactured	NanumetXR Tab. 50/500 mg	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
167	Manufactured	SITACOMBI XR 100/1000 mg	ILDONG PHARMACEUTICAL CO.,LTD.	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
168	Manufactured	SITACOMBI XR 50/1000 mg	ILDONG PHARMACEUTICAL CO.,LTD.	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
169	Manufactured	SITACOMBI XR 50/500 mg	ILDONG PHARMACEUTICAL CO.,LTD.	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
170	Manufactured	Janumetia XR Tab. 100/1000 mg	Sinil Pharm	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
171	Manufactured	Janumetia XR Tab. 50/1000 mg	Sinil Pharm	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
172	Manufactured	Janumetia XR Tab. 50/500 mg	Sinil Pharm	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
173	Manufactured	GL SitaMet XR tab. 100/1000 mg	GLPharmTech.	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
174	Manufactured	GL SitaMet XR tab. 50/1000 mg	GLPharmTech.	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
175	Manufactured	GL SitaMet XR tab. 50/500 mg	GLPharmTech.	2022-05-09	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
176	Manufactured	Sitdiem Met XR Tab. 100/1000 mg	Dongwha Pharm. Co., Ltd.	2022-05-10	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
177	Manufactured	Sitdiem Met XR Tab. 50/1000 mg	Dongwha Pharm. Co., Ltd.	2022-05-10	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
178	Manufactured	Sitdiem Met XR Tab. 50/500 mg	Dongwha Pharm. Co., Ltd.	2022-05-10	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
179	Manufactured	Glisitamet XR Tab. 100/1000 mg	DongKoo Bio&Pharma Co., Ltd.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
180	Manufactured	Glisitamet XR Tab. 50/1000 mg	DongKoo Bio&Pharma Co., Ltd.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
181	Manufactured	Glisitamet XR Tab. 50/500 mg	DongKoo Bio&Pharma Co., Ltd.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
182	Manufactured	Sitaoneplus XR Tab. 100/100 mg	Hana Pharm. Co., Ltd.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
183	Manufactured	Sitaoneplus XR Tab. 50/1000 mg	Hana Pharm. Co., Ltd.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
184	Manufactured	Sitaoneplus XR Tab. 50/500 mg	Hana Pharm. Co., Ltd.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
185	Manufactured	Sitakanmet XR Tab. 100/1000 mg	Dongkook Pharmaceutical	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
186	Manufactured	Sitakanmet XR Tab. 50/1000 mg	Dongkook Pharmaceutical	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
187	Manufactured	Sitakanmet XR Tab. 50/500 mg	Dongkook Pharmaceutical	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
188	Manufactured	Yoositamet XR Tab. 100/1000 mg	YooYoung Pharmaceutical Co., Ltd	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
189	Manufactured	Yoositamet XR Tab. 50/1000 mg	YooYoung Pharmaceutical Co., Ltd	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
190	Manufactured	Yoositamet XR Tab. 50/500 mg	YooYoung Pharmaceutical Co., Ltd	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
191	Manufactured	IGLIPTIN XR TAB. 100/1000 mg	Vivozon Pharm.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
192	Manufactured	IGLIPTIN XR TAB. 50/1000 mg	Vivozon Pharm.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
193	Manufactured	IGLIPTIN XR TAB. 50/500 mg	Vivozon Pharm.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
194	Manufactured	JANUDAUM-M XR TAB. 100/1000 mg	Daewoong Bio	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
195	Manufactured	JANUDAUM-M XR TAB. 50/1000 mg	Daewoong Bio	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
196	Manufactured	JANUDAUM-M XR TAB. 50/500 mg	Daewoong Bio	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
197	Manufactured	Januritin Combi XR Tab. 100/1000 mg	Daewon Pharm.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
198	Manufactured	Januritin Combi XR Tab. 50/1000 mg	Daewon Pharm.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
199	Manufactured	Januritin Combi XR Tab. 50/500 mg	Daewon Pharm.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
200	Manufactured	Fromet XR Tab. 100/1000 mg	AJU PHARM CO., LTD.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
201	Manufactured	Fromet XR Tab. 50/1000 mg	AJU PHARM CO., LTD.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
202	Manufactured	Fromet XR Tab. 50/500 mg	AJU PHARM CO., LTD.	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
203	Manufactured	Hanuvi M XR Tab. 100/1000 mg	Samjin Pharm	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
204	Manufactured	Hanuvi M XR Tab. 50/1000 mg	Samjin Pharm	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
205	Manufactured	Hanuvi M XR Tab. 50/500 mg	Samjin Pharm	2022-05-11	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
206	Manufactured	SITAFOR M XR Tab. 100/1000 mg	MOTHER'S PHARMACEUTICAL	2022-05-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
207	Manufactured	SITAFOR M XR Tab. 50/1000 mg	MOTHER'S PHARMACEUTICAL	2022-05-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
208	Manufactured	SITAFOR M XR Tab. 50/500 mg	MOTHER'S PHARMACEUTICAL	2022-05-12	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
209	Manufactured	Glusitaduo XR Tablet 100/1000 mg	HANALL BIOPHARMA CO., LTD.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
210	Manufactured	Glusitaduo XR Tablet 50/1000 mg	HANALL BIOPHARMA CO., LTD.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
211	Manufactured	Glusitaduo XR Tablet 50/500 mg	HANALL BIOPHARMA CO., LTD.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
212	Manufactured	Sitaglminduo XR Tablet 50/500 mg	Korea Arlico Pharm Co., Ltd.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
213	Manufactured	Sitaglminduo XR Tablet 100/1000 mg	Korea Arlico Pharm Co., Ltd.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
214	Manufactured	Sitaglminduo XR Tablet 50/1000 mg	Korea Arlico Pharm Co., Ltd.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
215	Manufactured	Sitaformin XR Tab. 100/1000 mg	Daehan New Pharm	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
216	Manufactured	Sitaformin XR Tab. 50/1000 mg	Daehan New Pharm	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
217	Manufactured	Sitaformin XR Tab. 50/500 mg	Daehan New Pharm	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
218	Manufactured	A-sitamet XR Tab. 100/1000 mg	Ahn-Gook Pharmaceutical	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
219	Manufactured	A-sitamet XR Tab. 50/1000 mg	Ahn-Gook Pharmaceutical	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
220	Manufactured	A-sitamet XR Tab. 50/500 mg	Ahn-Gook Pharmaceutical	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
221	Manufactured	Teramet XR Tab. 100/1000 mg	THERAGEN ETEX CO., LTD.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
222	Manufactured	Teramet XR Tab. 50/1000 mg	THERAGEN ETEX CO., LTD.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
223	Manufactured	Teramet XR Tab. 50/500 mg	THERAGEN ETEX CO., LTD.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
224	Manufactured	TRUSita M XR 100/1000 mg	Boryung Co., Ltd.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
225	Manufactured	TRUSita M XR 50/1000 mg	Boryung Co., Ltd.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
226	Manufactured	TRUSita M XR 50/500 mg	Boryung Co., Ltd.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
227	Manufactured	Forminsita SR Tab. 100/1000 mg (sitagliptin hydrochloride hydrate, metformin hydrochloride)	GC Biopharma Corp.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
228	Manufactured	Forminsita SR Tab. 50/1000 mg (sitagliptin hydrochloride hydrate, metformin hydrochloride)	GC Biopharma Corp.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
229	Manufactured	Forminsita SR Tab. 50/500 mg (sitagliptin hydrochloride hydrate, metformin hydrochloride)	GC Biopharma Corp.	2022-05-13	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
230	Manufactured	SitagliduoXR tab. 100/1000 mg	Daewoo Pharm	2022-05-16	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
231	Manufactured	SitagliduoXR tab. 50/1000 mg	Daewoo Pharm	2022-05-16	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
232	Manufactured	SitagliduoXR tab. 50/500 mg	Daewoo Pharm	2022-05-16	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
233	Manufactured	Sitaro M XR 100/1000 mg (sitagliptin hydrochloride hydrate, metformin hydrochloride)	Hanlim Pharm. Co., Ltd.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
234	Manufactured	Sitaro M XR 50/1000 mg (sitagliptin hydrochloride hydrate, metformin hydrochloride)	Hanlim Pharm. Co., Ltd.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
235	Manufactured	Sitaro M XR 50/500 mg (sitagliptin hydrochloride hydrate, metformin hydrochloride)	Hanlim Pharm. Co., Ltd.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
236	Manufactured	Xmet XR tablet 100/1000 mg	GENUONE Sciences Inc.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
237	Manufactured	Xmet XR tablet 50/1000 mg	GENUONE Sciences Inc.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
238	Manufactured	Xmet XR tablet 50/500 mg	GENUONE Sciences Inc.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
239	Manufactured	JanumaxM XR Tab. 100/1000 mg	Samik Pharmaceutical Co., Ltd.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
240	Manufactured	JanumaxM XR Tab. 50/1000 mg	Samik Pharmaceutical Co., Ltd.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
241	Manufactured	JanumaxM XR Tab. 50/500 mg	Samik Pharmaceutical Co., Ltd.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
242	Manufactured	Janu-M-Met XR Tablet 100/1000 mg	HLB Pharmaceutical Co., Ltd.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
243	Manufactured	Janu-M-Met XR Tablet 50/1000 mg	HLB Pharmaceutical Co., Ltd.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
244	Manufactured	Janu-M-Met XR Tablet 50/500 mg	HLB Pharmaceutical Co., Ltd.	2022-05-17	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
245	Manufactured	Atenel-M SR Tab. 10/500 mg	Ahn-Gook Pharmaceutical	2022-05-23	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
246	Manufactured	Atenel-M SR Tab. 10/750 mg	Ahn-Gook Pharmaceutical	2022-05-23	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
247	Manufactured	Atenel-M SR Tab. 20/1000 mg	Ahn-Gook Pharmaceutical	2022-05-23	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
248	Manufactured	Teneglo M SR Tab. 10/500 mg	Il Hwa	2022-05-25	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
249	Manufactured	Teneglo M SR Tab. 10/750 mg	Il Hwa	2022-05-25	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
250	Manufactured	Teneglo M SR Tab. 20/1000 mg	Il Hwa	2022-05-25	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
251	Manufactured	Dapalon Duo SR Tab. 10/1000 mg	Hanmi Pharm. Co., Ltd.	2022-06-15	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin Bis L-proline
252	Manufactured	Dapalon Duo SR Tab. 10/500 mg	Hanmi Pharm. Co., Ltd.	2022-06-15	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin Bis L-proline
253	Manufactured	Dapalon Duo SR Tab. 5/1000 mg	Hanmi Pharm. Co., Ltd.	2022-06-15	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin Bis L-proline
254	Manufactured	Dapalon Duo SR Tab. 5/500 mg	Hanmi Pharm. Co., Ltd.	2022-06-15	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin Bis L-proline
255	Manufactured	TD combi tab. 10/100 mg	TDS Pharm. Co., Ltd..	2022-06-15	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride hydrate Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
256	Manufactured	Tenegli M SR Tab 10/500 mg	GENUONE Sciences Inc.	2022-06-27	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
257	Manufactured	Tenegli M SR Tab 10/750 mg	GENUONE Sciences Inc.	2022-06-27	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
258	Manufactured	Tenegli M SR Tab 20/1000 mg	GENUONE Sciences Inc.	2022-06-27	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
259	Manufactured	Terigglemet XR Tab. 10/500 mg	SHIN POONG PHARM. CO., LTD	2022-06-28	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
260	Manufactured	Tenedia SR Tablet 10/500 mg	GENUPharma Inc.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
261	Manufactured	Tenedia SR Tablet 10/750 mg	GENUPharma Inc.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
262	Manufactured	Tenedia SR Tablet 20/1000 mg	GENUPharma Inc.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
263	Manufactured	Tenerotin-M ER Tab 10/500 mg	KMS Pharmaceutical Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
264	Manufactured	Tenerotin-M ER Tab 10/750 mg	KMS Pharmaceutical Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
265	Manufactured	Tenerotin-M ER Tab 20/1000 mg	KMS Pharmaceutical Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
266	Manufactured	Tenelikan M SR Tab. 10/500 mg	Dongkook Pharmaceutical	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
267	Manufactured	Tenelikan M SR Tab. 10/750 mg	Dongkook Pharmaceutical	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
268	Manufactured	Tenelikan M SR Tab. 20/1000 mg	Dongkook Pharmaceutical	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
269	Manufactured	Tenephilplus SR Tab. 10/500 mg	JEIL PHARMACEUTICAL CO., LTD.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
270	Manufactured	Tenephilplus SR Tab. 10/750 mg	JEIL PHARMACEUTICAL CO., LTD.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
271	Manufactured	Tenephilplus SR Tab. 20/1000 mg	JEIL PHARMACEUTICAL CO., LTD.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
272	Manufactured	Tenelord M SR Tab. 10/500 mg	Daewoong Bio	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
273	Manufactured	Tenelord M SR Tab. 10/750 mg	Daewoong Bio	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
274	Manufactured	Tenelord M SR Tab. 20/1000 mg	Daewoong Bio	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
275	Manufactured	Teneliel Duo SR Tab. 10/500 mg	GL Pharma	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
276	Manufactured	Teneliel Duo SR Tab. 10/750 mg	GL Pharma	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
277	Manufactured	Teneliel Duo SR Tab. 20/1000 mg	GL Pharma	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
278	Manufactured	Tenellitak Duo SR. 10/500 mg	LitePharmTech Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
279	Manufactured	Tenellitak Duo SR. 10/750 mg.	LitePharmTech Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
280	Manufactured	Tenellitak Duo SR. 20/1000 mg	LitePharmTech Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
281	Manufactured	Terigglemet XR Tab. 10/750 mg	SHIN POONG PHARM. CO., LTD	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
282	Manufactured	Terigglemet XR Tab. 20/1000 mg	SHIN POONG PHARM. CO., LTD	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
283	Manufactured	Telia M SR Tab. 10/500 mg	GUJU Pharm Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
284	Manufactured	Telia M SR Tab. 10/750 mg	GUJU Pharm Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
285	Manufactured	Telia M SR Tab. 20/1000 mg	GUJU Pharm Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
286	Manufactured	Terium M SR Tab. 10/500 mg	Hana Pharm. Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
287	Manufactured	Terium M SR Tab. 10/750 mg	Hana Pharm. Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
288	Manufactured	Terium M SR Tab. 20/1000 mg	Hana Pharm. Co., Ltd.	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
289	Manufactured	Teliptin-M SR Tab. 10/500 mg	YUNGJIN PHARM. CO., LTD	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
290	Manufactured	Teliptin-M SR Tab. 10/750 mg	YUNGJIN PHARM. CO., LTD	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate
291	Manufactured	Teliptin-M SR Tab. 20/1000 mg	YUNGJIN PHARM. CO., LTD	2022-07-01	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin ditosylate dihydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
292	Manufactured	TenelyM SR Tab. 10/500 mg	KyungDong Pharm.	2022-07-06	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
293	Manufactured	TenelyM SR Tab. 10/750 mg	KyungDong Pharm.	2022-07-06	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
294	Manufactured	TenelyM SR Tab. 20/1000 mg	KyungDong Pharm.	2022-07-06	Antidiabetics	Teneligliptin hydrobromide hydrate → Teneligliptin hydrochloride hydrate
295	Manufactured	Dapapro Tablet 10 mg (dapagliflozin formate)	DONG-A ST	2022-08-23	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin formate
296	Manufactured	Dapapro Tablet 5 mg (dapagliflozin formate)	DONG-A ST	2022-08-23	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin formate
297	Manufactured	Dapa N Duo XR Tab. 10/500 mg	HK inno.N corporation	2022-11-08	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
298	Manufactured	Dapa N Duo XR Tab. 5/500 mg	HK inno.N corporation	2022-11-08	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
299	Manufactured	Damet XR Tab. 10/500 mg	Binex	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
300	Manufactured	Damet XR Tab. 5/500 mg	Binex	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
301	Manufactured	Duo Rich XR tab. 10/500 mg	RICHWOOD TRADING COMPANY, LTD.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
302	Manufactured	Duo Rich XR tab. 5/500 mg	RICHWOOD TRADING COMPANY, LTD.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
303	Manufactured	Ilyang Dapame XR Tab. 10/500 mg	IL-YANG PHARM.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
304	Manufactured	Ilyang Dapame XR Tab. 5/500 mg	IL-YANG PHARM.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
305	Manufactured	K-duo SR tab. 10/500 mg	KS Pharm. Inc.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
306	Manufactured	K-duo SR tab. 5/500 mg	KS Pharm. Inc.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
307	Manufactured	Forglimet XR 10/500 mg	Korea Prime Pharm.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
308	Manufactured	Forglimet XR 5/500 mg	Korea Prime Pharm.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
309	Manufactured	Fosuvetduo XR Tab. 10/500 mg	GENUONE Sciences Inc.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
310	Manufactured	Fosuvetduo XR Tab. 5/500 mg	GENUONE Sciences Inc.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
311	Manufactured	ForxiDCM SR Tab. 10/500 mg	Kukje Pharm.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
312	Manufactured	ForxiDCM SR Tab. 5/500 mg	Kukje Pharm.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
313	Manufactured	Forximet XR tab. 10/500 mg	WITHUS PHARMACEUTICAL CO., LTD.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
314	Manufactured	Forximet XR tab. 5/500 mg	WITHUS PHARMACEUTICAL CO., LTD.	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
315	Manufactured	FlogaDuo SR Tab. 10/500 mg	Nexpharm Korea	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
316	Manufactured	FlogaDuo SR Tab. 5/500 mg	Nexpharm Korea	2022-11-10	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
317	Manufactured	DapawonM XR Tab. 10/1000 mg	Daewon Pharm.	2022-11-16	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
318	Manufactured	DapawonM XR Tab. 10/500 mg	Daewon Pharm.	2022-11-18	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
319	Manufactured	DapawonM XR Tab. 5/1000 mg	Daewon Pharm.	2022-11-18	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
320	Manufactured	DapawonM XR Tab. 5/500 mg	Daewon Pharm.	2022-11-18	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
321	Manufactured	Exiaban Tab. 60 mg (edoxaban besylate hydrate)	GENUONE Sciences Inc.	2022-12-01	Anti-coagulants	Edoxaban tosilate hydrate → Edoxaban besylate hydrate
322	Manufactured	DapaprozinMet XR Tab. 10/1000 mg	DongKoo Bio&Pharma Co., Ltd.	2022-12-05	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
323	Manufactured	DapaprozinMet XR Tab. 10/500 mg	DongKoo Bio&Pharma Co., Ltd.	2022-12-05	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
324	Manufactured	DapaprozinMet XR Tab. 5/1000 mg	DongKoo Bio&Pharma Co., Ltd.	2022-12-05	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
325	Manufactured	DapaprozinMet XR Tab. 5/500 mg	DongKoo Bio&Pharma Co., Ltd.	2022-12-05	Antidiabetics	Dapagliflozin -12-propanediol hydrate → Dapagliflozin citric acid
326	Manufactured	Megaxaban tab. 60 mg (edoxaban besylate hydrate)	Handok Inc.	2022-12-05	Anti-coagulants	Edoxaban tosilate hydrate → Edoxaban besylate hydrate
327	Manufactured	Enxiana Tab. 60 mg (edoxaban besylate hydrate)	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-12-05	Anti-coagulants	Edoxaban tosilate hydrate → Edoxaban besylate hydrate
328	Manufactured	Janumetia Tab. 50/1000 mg	Sinil Pharm	2022-12-05	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
329	Manufactured	Janumetia Tab. 50/500 mg	Sinil Pharm	2022-12-05	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
330	Manufactured	Janumetia Tab. 50/850 mg	Sinil Pharm	2022-12-05	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
331	Manufactured	Genupharma Edoxaban Tab. 60 mg (edoxaban besylate hydrate)	GENUPharma Inc.	2022-12-05	Anti-coagulants	Edoxaban tosilate hydrate → Edoxaban besylate hydrate
332	Manufactured	Vemlia Tab (tenofovir alafenamide citrate)	DONG-A ST	2022-12-15	Liver disease drugs	Tenofovir alafenamide hemi-fumarate → Tenofovir alafenamide citrate
333	Manufactured	Bepotin SR Tab. (Bepotastine besilate)	DongKoo Bio&Pharma Co., Ltd.	2022-12-16	Antihistamines	Bepotastine salicylate → Bepotastine besylate
334	Manufactured	Glusitaduo Tab. 50/1000 mg	HANALL BIOPHARMA CO., LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
335	Manufactured	Glusitaduo Tab. 50/500 mg	HANALL BIOPHARMA CO., LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
336	Manufactured	Glusitaduo Tab. 50/850 mg	HANALL BIOPHARMA CO., LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
337	Manufactured	Glisitamet Tab. 50/1000 mg	DongKoo Bio&Pharma Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
338	Manufactured	Glisitamet Tab. 50/500 mg	DongKoo Bio&Pharma Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
339	Manufactured	Glisitamet Tab. 50/850 mg	DongKoo Bio&Pharma Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
340	Manufactured	Nanumet Tab. 50/1000 mg	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
341	Manufactured	Nanumet Tab. 50/500 mg	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
342	Manufactured	Nanumet Tab. 50/850 mg	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
343	Manufactured	Dulion SR Tab. (bepotastine besilate)	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-12-21	Antihistamines	Bepotastine salicylate → Bepotastine besylate
344	Manufactured	Bepo M SR Tab. (bepotastine besilate)	MOTHER'S PHARMACEUTICAL	2022-12-21	Antihistamines	Bepotastine salicylate → Bepotastine besylate
345	Manufactured	Bepotaon SR Tab. (bepotastine besilate)	Myungmoon Pharm.	2022-12-21	Antihistamines	Bepotastine salicylate → Bepotastine besylate
346	Manufactured	Bef XR tablet (bepotastine besilate)	SHIN POONG PHARM. CO., LTD	2022-12-21	Antihistamines	Bepotastine salicylate → Bepotastine besylate
347	Manufactured	Sitaglimet Tab. 50/1000 mg	Dongwha Pharm. Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
348	Manufactured	Sitaglimet Tab. 50/500 mg	Dongwha Pharm. Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
349	Manufactured	Sitaglimet Tab. 50/850 mg	Dongwha Pharm. Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
350	Manufactured	TRUSita M Tab. 50/1000 mg	GL Pharma	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
351	Manufactured	TRUSita M Tab. 50/500 mg	GL Pharma	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
352	Manufactured	TRUSita M Tab. 50/850 mg	GL Pharma	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
353	Manufactured	Sitaoneplus Tab. 50/1000 mg (sitagliptin, metformin)	Hana Pharm. Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
354	Manufactured	Sitaoneplus Tab. 50/500 mg (sitagliptin, metformin)	Hana Pharm. Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
355	Manufactured	Sitaoneplus Tab. 50/850 mg (sitagliptin, metformin)	Hana Pharm. Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
356	Manufactured	Sitacombi Tablet 50/1000 mg	ILDONG PHARMACEUTICAL CO.,LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
357	Manufactured	Sitacombi Tablet 50/500 mg	ILDONG PHARMACEUTICAL CO.,LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
358	Manufactured	Sitacombi Tablet 50/850 mg	ILDONG PHARMACEUTICAL CO.,LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
359	Manufactured	SITAFORM TAB. 50/1000 mg	MOTHER'S PHARMACEUTICAL	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
360	Manufactured	SITAFORM TAB. 50/500 mg	MOTHER'S PHARMACEUTICAL	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
361	Manufactured	SITAFORM TAB. 50/850 mg	MOTHER'S PHARMACEUTICAL	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
362	Manufactured	Xmet tablet 50/1000 mg	GENUONE Sciences Inc.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
363	Manufactured	Xmet tablet 50/500 mg	GENUONE Sciences Inc.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
364	Manufactured	Xmet tablet 50/850 mg	GENUONE Sciences Inc.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
365	Manufactured	Unibepota SR Tab. (bepotastine besilate)	Union Korea Pharm Co., Ltd.	2022-12-21	Antihistamines	Bepotastine salicylate → Bepotastine besylate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
366	Manufactured	Yoositamet Tab. 50/1000 mg	YooYoung Pharmaceutical Co., Ltd	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
367	Manufactured	Yoositamet Tab. 50/500 mg	YooYoung Pharmaceutical Co., Ltd	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
368	Manufactured	Yoositamet Tab. 50/850 mg	YooYoung Pharmaceutical Co., Ltd	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
369	Manufactured	Igliptin IR Tab. 50/1000 mg	Vivozon Pharm.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
370	Manufactured	Igliptin IR Tab. 50/500 mg	Vivozon Pharm.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
371	Manufactured	Igliptin IR Tab. 50/850 mg	Vivozon Pharm.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
372	Manufactured	Eposan SR Tab. (bepotastine besilate)	Edenpahrma	2022-12-21	Antihistamines	Bepotastine salicylate → Bepotastine besylate
373	Manufactured	Janu-M-Met Tablet 50/1000 mg	HLB Pharmaceutical Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
374	Manufactured	Janu-M-Met Tablet 50/500 mg	HLB Pharmaceutical Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
375	Manufactured	Janu-M-Met Tablet 50/850 mg	HLB Pharmaceutical Co., Ltd.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
376	Manufactured	Talimin SR Tab. (bepotastine besilate)	YUNGJIN PHARM. CO., LTD	2022-12-21	Antihistamines	Bepotastine salicylate → Bepotastine besylate
377	Manufactured	TABEON SR Tab. (bepotastine besilate)	Kukje Pharm.	2022-12-21	Antihistamines	Bepotastine salicylate → Bepotastine besylate
378	Manufactured	Promet tab. 50/1000 mg	AJU PHARM CO., LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
379	Manufactured	Promet tab. 50/500 mg	AJU PHARM CO., LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
380	Manufactured	Promet tab. 50/850 mg	AJU PHARM CO., LTD.	2022-12-21	Antidiabetics	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

No.	Manufactured /Imported	Product Name	Company	Approval Date	Detailed Class.	Remarks
381	Manufactured	ARDEWKA 30/2.5 mg Tablet	Korea Arlico Pharm Co., Ltd.	2022-12-27	Antihyperten sives	Sitaglijptin phosphate hydrate → Sitagliptin hydrochloride monohydrate
382	Manufactured	ARDEWKA 60/2.5 mg Tablet	Korea Arlico Pharm Co., Ltd.	2022-12-27	Antihyperten sives	Sitagliptin phosphate hydrate → Sitagliptin hydrochloride monohydrate

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

2.4.2. Drugs in New Therapeutic Class

There were two drugs approved in new therapeutic class, one was manufactured item and the other was imported item: one drug for improving hyperphosphatemia in chronic kidney disease patients, and the other one targeting gastric mucosal lesions in acute and chronic gastritis patients (refer to Table 34).

Table 34. Drugs Requiring Data Submission in New Therapeutic Class Approved in 2022

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Efficacy/ Effectiveness
1	Imported	Nephoxil capsule 500 mg (Iron(III) citrate hydrate)	Kyowa Kirin Korea Co., Ltd	2022-05-09	Miscellaneous circulatory system drugs	Improvement of hyperphosphatemia in patients with chronic kidney disease undergoing hemodialysis
2	Manufactured	Esomezol DR SR Cap. 10 mg (esomeprazole magnesium trihydrate)	Hanmi Pharm. Co., Ltd.	2022-09-30	Peptic ulcer drugs	Improvement of gastric mucosal lesions in acute and chronic gastritis

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

101 drugs with new composition (100 manufactured items and 1 imported item) were approved, with circulatory system drugs accounting for the majority (49 items, 48.5%). Among the drugs with new composition, 30 hypertension/hyperlipidemia combination drugs were approved (29.7%), 11 hyperlipidemia combination drugs (10.9%), and 8 hypertension combination drugs (7.9%) were approved. At the time of arranging them according to their ingredients, 29 combination drugs(hypertension/hyperlipidemia or hyper lipidemia) with ezetimibe were approved (28.7%), representing 59.2% of the

approved circulatory system drugs with new composition in 2022. While, the majority of the anti-diabetics with new composition (30 items) were approved as a combination drugs (29 items) of sitagliptin phosphate hydrate and dapagliflozin propanediol hydrate (refer to Table 35).

29 items with change in strength were newly approved (22 manufactured items and 7 imported items), and drugs with various efficacy newly approved as ones with change in strength are as follows: 6 items of peptic ulcer drugs, 5 items of protein amino acid preparations, 3 items of psychotropics, 3 items of antipyretics, analgesic and anti-inflammatory drugs, and 2 items of drugs for atherosclerosis, 2 items of certified therapeutic agent, 1 item of antitussive expectorant, 1 item of adrenal hormone, 1 item of miscellaneous circulatory system drug, 1 item of miscellaneous respiratory system drug, 1 item of miscellaneous central nervous system drug, 1 item of miscellaneous chemotherapeutic agents, 1 item of vitamin A and D preparations, 1 item of drug acting mainly on gram-positive/negative bacteria, rickettsia, and virus (refer to Table 36).

Table 35. Drugs Requiring Data Submission with New Composition Approved in 2022

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
1	Manufactured	GLOTAPA tab. 10/100 mg	ILDONG PHARMACEUTICAL CO.,LTD.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
2	Manufactured	Gluduo Tab. 10/100 mg	GUJU Pharm Co., Ltd.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
3	Manufactured	DAPAGREEN-S TAB. 10/100 mg	JINYANG PHARM CO., LTD.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
4	Manufactured	Dapaduotablet 10/100 mg	Daewoo Pharm	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
5	Manufactured	Daparoutine Star Tablet 10/100 mg	SHIN POONG PHARM. CO., LTD	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
6	Manufactured	DAPARILSITA Tab. 10/100 mg	AJU PHARM CO., LTD.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
7	Manufactured	Dapavia Tab. 10/100 mg	Aprogen Biologics Inc.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
8	Manufactured	Dapasi Tab. 10/100 mg (dapagliflozin propanediol hydrate, Sitagliptin phosphate hydrate)	REYON PHARMACEUTICAL CO., LTD	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
9	Manufactured	Dapajanu Tab. 10/100 mg	Myungmoon Pharm.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
10	Manufactured	Daforga Plus Tab. 10/100 mg	Sam Chun Dang Pharm	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
11	Manufactured	SiDapflo Tab. 10/100 mg	YUNGJIN PHARM. CO., LTD	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
12	Manufactured	SIDAFLO Tabs. 10/100mg(dapagliflozin / sitagliptin)	Dongkwang Pharm.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
13	Manufactured	Sitadapa Tab. 10/100 mg	GC Biopharma Corp.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
14	Manufactured	Sitaone Duo Tab. 10/100 mg	Hana Pharm. Co., Ltd.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
15	Manufactured	Jaglozin tab. 10/100 mg	Neo Bio Korea Pharm. Co., Ltd.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
16	Manufactured	Januga Tab. 10/100 mg (dapagliflozin, sitagliptin)	IL-YANG PHARM.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
17	Manufactured	JANUDAJIN Tab. 10/100 mg	PharmGen Science, Inc.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
18	Manufactured	Janudapa Tab. 10/100 mg	Sinil Pharm	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
19	Manufactured	TAPADUO TAB 10/100 mg	DAEHWA Pharm	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
20	Manufactured	Forxidabae Tab. 10/100 mg	LitePharmTech Co., Ltd.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
21	Manufactured	FORXIVIS 10/100 mg	Kukje Pharm.	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
22	Manufactured	Forxivia Tab. 10/100 mg	Binex	2022-01-04	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
23	Manufactured	GlyduoQ Tab. 10/100MG	SUNGYI BIO CO., LTD.	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
24	Manufactured	Glilowsit Tab. 10/100 mg	Il Hwa	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
25	Manufactured	Daglosita Tablet 10/100 mg	Korea Arlico Pharm Co., Ltd.	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
26	Manufactured	Dapaglesita Tab. 10/100 mg	MEDICA KOREA Co., Ltd.	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
27	Manufactured	Daparsi Tab 10/100 mg	Hwail Pharam. Co., Ltd.	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
28	Manufactured	Sitakandapeul Tablet 10/100 mg	Dongkook Pharmaceutical	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
29	Manufactured	Posarin Plus Tab. 10/100 mg	Whan In Pharm.	2022-01-12	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin propanediol hydrate
30	Manufactured	CANTABELL A tab. 16/10/40 mg	Chong Kun Dang Pharm.	2022-01-24	Miscellaneous circulatory system drugs	Candesartan cilexetil Atorvastatin calcium trihydrate Amlodipine besylate
31	Manufactured	CANTABELL A tab. 16/5/10 mg	Chong Kun Dang Pharm.	2022-01-24	Miscellaneous circulatory system drugs	Candesartan cilexetil Atorvastatin calcium trihydrate Amlodipine besylate
32	Manufactured	CANTABELL A tab. 16/5/20 mg	Chong Kun Dang Pharm.	2022-01-24	Miscellaneous circulatory system drugs	Candesartan cilexetil Atorvastatin calcium trihydrate Amlodipine besylate
33	Manufactured	CANTABELL A tab. 8/5/10 mg	Chong Kun Dang Pharm.	2022-01-24	Miscellaneous circulatory system drugs	Candesartan cilexetil Atorvastatin calcium trihydrate Amlodipine besylate
34	Manufactured	CANTABELL A tab. 8/5/20 mg	Chong Kun Dang Pharm.	2022-01-24	Miscellaneous circulatory system drugs	Candesartan cilexetil Atorvastatin calcium trihydrate Amlodipine besylate
35	Manufactured	Rabenew Tabs 20/500 mg	YUNGJIN PHARM. CO., LTD	2022-01-27	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
36	Manufactured	RABEDUET Tab. 20/500 mg	Dongwha Pharm. Co., Ltd.	2022-01-27	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
37	Manufactured	Rabemore Tab. 20/500 mg	Whan In Pharm.	2022-01-27	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
38	Manufactured	Rabeol Duo Tab. 20/500 mg	Samjin Pharm	2022-01-27	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
39	Manufactured	Rabiduo Tablet 20/500 mg	DONG-A ST	2022-01-27	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
40	Manufactured	Rabietduo Tablets 20/500 mg	ILDONG PHARMACEUTICAL CO.,LTD.	2022-01-27	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
41	Manufactured	RABEDUO Tab. 20/800 mg	Korea United Pharm. Inc.	2022-01-28	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
42	Manufactured	RABECOMBI Tab.	Korea Biochem Pharm	2022-02-08	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
43	Manufactured	RabepTop Tab. 20/800 mg	Hanlim Pharm. Co., Ltd.	2022-02-08	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
44	Manufactured	Nutrihexamin Injection	DAI HAN PHARM CO., LTD.	2022-02-15	Protein and amino acid preparations	L-methionine Glycine L-serine L-aspartic acid L-glutamic acid L-proline L-cysteine L-isoleucine L-tryptophan L-valine L-histidine L-alanine L-tyrosine L-lysine acetate L-leucine L-threonine L-arginine L-phenylalanine
45	Manufactured	Esomezole plus Tab. 20/350 mg	Hanmi Pharm. Co., Ltd.	2022-03-21	Peptic ulcer drugs	Esomeprazole Magnesium trihydrate Magnesium hydroxide
46	Manufactured	Ibupopremix Injection (ibuprofen)	GENUONE Sciences Inc.	2022-04-07	Antipyretics, analgesics, and anti-inflammatory drugs	Ibuprofen
47	Manufactured	Duowell A Plus Tablet 40/10/10/5 mg	YUHAN Coporation	2022-05-20	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
48	Manufactured	Duowell A Plus Tablet 40/20/10/5 mg	YUHAN Coporation	2022-05-20	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
49	Manufactured	Duowell A Plus Tablet 40/5/10/5 mg	YUHAN Coporation	2022-05-20	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
50	Manufactured	Duowell A Plus Tabelt 80/10/10/5 mg	YUHAN Coporation	2022-05-20	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
51	Manufactured	Duowell A Plus Tablet 80/20/10/5 mg	YUHAN Coporation	2022-05-20	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
52	Manufactured	Duowell A Plus Tablet 80/5/10/5 mg	YUHAN Coporation	2022-05-20	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
53	Manufactured	Rozetelpine Tab. 40/10/10/5 mg	GC Biopharma Corp.	2022-05-23	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
54	Manufactured	Rozetelpine Tab. 40/20/10/5 mg	GC Biopharma Corp.	2022-05-23	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
55	Manufactured	Rozetelpine Tab. 40/5/10/5 mg	GC Biopharma Corp.	2022-05-23	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
56	Manufactured	Rozetelpine Tab. 80/10/10/5 mg	GC Biopharma Corp.	2022-05-23	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
57	Manufactured	Rozetelpine Tab. 80/20/10/5 mg	GC Biopharma Corp.	2022-05-23	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
58	Manufactured	Rozetelpine Tab. 80/5/10/5 mg	GC Biopharma Corp.	2022-05-23	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
59	Imported	ACTOSED PA POWDER (sodium percarbonate)	JunPharm	2022-05-23	Miscellaneous drugs for public hygiene	Sodium percarbonate
60	Manufactured	TELMIROZET tab. 40/10/10 mg	Chong Kun Dang Pharm.	2022-05-24	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium
61	Manufactured	TELMIROZET tab. 40/20/10 mg	Chong Kun Dang Pharm.	2022-05-24	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
62	Manufactured	TELMIROZET tab. 40/5/10 mg	Chong Kun Dang Pharm.	2022-05-24	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium
63	Manufactured	Closartan Tab. 100/12.5 mg (losartan potassium, chlorthalidone)	Hanmi Pharm. Co., Ltd.	2022-05-31	Antihypertensives	Chlorthalidone Losartan potassium
64	Manufactured	Closartan Tab. 50/12.5 mg (losartan potassium, chlorthalidone)	Hanmi Pharm. Co., Ltd.	2022-05-31	Antihypertensives	Chlorthalidone Losartan potassium
65	Manufactured	Ezesupra Tab. (ezetimibe, fenofibrate)	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-06-20	Antiarteriosclerotic agents	Fenofibrate Ezetimibe
66	Manufactured	Fenozetibe Tab.	Alvogen Korea	2022-06-23	Antiarteriosclerotic agents	Fenofibrate Ezetimibe
67	Manufactured	Rabetan tab. 20/800 mg	KOREA PHARMA Co., Ltd.	2022-06-30	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
68	Manufactured	RABEBICA Tab. 20/800 mg	Daewoong Bio	2022-07-04	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
69	Manufactured	RABEUMDUO Tab. 20/800 mg	MEDICA KOREA Co., Ltd.	2022-07-04	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
70	Manufactured	PARA DUO Tablet 20/800 mg	Dasan Pharmaceutical Co., Ltd.	2022-07-04	Peptic ulcer drugs	Rabeprazole sodium Sodium bicarbonate
71	Manufactured	Atomega Soft Cap. 5/1000 mg	Kuhnil Pharmaceutical Co., Ltd.	2022-07-05	Antiarteriosclerotic agents	Omega-3-acid ethyl esters 90 Atorvastatin calcium trihydrate
72	Manufactured	Newtomega Soft Cap. 5/1000 mg	Daehan New Pharm	2022-07-08	Antiarteriosclerotic agents	Omega-3-acid ethyl esters 90 Atorvastatin calcium trihydrate
73	Manufactured	Atocoma soft cap. 5/1000 mg	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-07-08	Antiarteriosclerotic agents	Omega-3-acid ethyl esters 90 Atorvastatin calcium tihydrate
74	Manufactured	Uromega soft cap. 5/1000 mg (atorvastatin, omega-3-acid ethyl esters 90)	Kuhnilbiopharm. Co., Ltd.	2022-07-08	Antiarteriosclerotic agents	Omega-3-acid ethyl esters 90 Atorvastatin calcium tihydrate
75	Manufactured	Pentomega Soft Capsule 5/1000 mg	Penmix Ltd.	2022-07-08	Antiarteriosclerotic agents	Omega-3-acid ethyl esters 90 Atorvastatin calcium tihydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
76	Manufactured	ExigluS Tab.	Chong Kun Dang Pharm.	2022-07-11	Antidiabetics	Sitagliptin phosphate hydrate Dapagliflozin
77	Manufactured	NUVOROZET tab. 40/2.5/10/10 mg	Chong Kun Dang Pharm.	2022-07-20	Miscellaneous circulatory system drugs	Rosuvastatin calcium (micronized) Telmisartan Ezetimibe S-amlodipine besylate dihydrate
78	Manufactured	NUVOROZET tab. 40/2.5/5/10 mg	Chong Kun Dang Pharm.	2022-07-20	Miscellaneous circulatory system drugs	Rosuvastatin calcium (micronized) Telmisartan Ezetimibe S-amlodipine besylate dihydrate
79	Manufactured	NUVOROZET tab. 40/5/10/10 mg	Chong Kun Dang Pharm.	2022-07-20	Miscellaneous circulatory system drugs	Rosuvastatin calcium (micronized) Telmisartan Ezetimibe S-amlodipine besylate dihydrate
80	Manufactured	NUVOROZET tab. 40/5/5/10 mg	Chong Kun Dang Pharm.	2022-07-20	Miscellaneous circulatory system drugs	Rosuvastatin calcium (micronized) Telmisartan Ezetimibe S-amlodipine besylate dihydrate
81	Manufactured	ATMEGCombiGel Soft Capsule 5/1000 mg	Korea United Pharm. Inc.	2022-07-21	Antiarteriosclerotic agents	Omega-3-acid ethyl esters 90 Atorvastatin calcium trihydrate
82	Manufactured	TELMICANQ Tab. 40/10/10/5 mg	JEIL PHARMACEUTICAL CO., LTD.	2022-07-21	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
83	Manufactured	TELMICANQ Tab. 40/20/10/5 mg	JEIL PHARMACEUTICAL CO., LTD.	2022-07-21	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
84	Manufactured	TELMICANQ Tab. 40/5/10/5 mg	JEIL PHARMACEUTICAL CO., LTD.	2022-07-21	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
85	Manufactured	TELMICANQ Tab. 80/10/10/5 mg	JEIL PHARMACEUTICAL CO., LTD.	2022-07-21	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
86	Manufactured	TELMICANQ Tab. 80/20/10/5 mg	JEIL PHARMACEUTICAL CO., LTD.	2022-07-21	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
87	Manufactured	TELMICANQ Tab. 80/5/10/5 mg	JEIL PHARMACEUTICAL CO., LTD.	2022-07-21	Miscellaneous circulatory system drugs	Ezetimibe (micronized) Telmisartan Rosuvastatin calcium Amlodipine besylate
88	Manufactured	ATROMEGA CombiGel Soft caps. 5/1000 mg	Korea Biochem Pharm	2022-07-25	Antiarteriosclerotic agents	Atorvastatin calcium trihydrate Omega-3-acid ethyl esters 90
89	Manufactured	Crezet Tab. 10/2.5 mg	Daewoong Pharmaceuticals	2022-08-04	Antiarteriosclerotic agents	Rosuvastatin calcium Ezetimibe
90	Manufactured	EPESINACE TAB.	Myungmoon Pharm.	2022-09-22	Antipyretics, analgesics, and anti-inflammatory drugs	Aceclofenac Eperisone hydrochloride
91	Manufactured	Epeclonic Tab.	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-09-22	Antipyretics, analgesics, and anti-inflammatory drugs	Aceclofenac Eperisone hydrochloride
92	Manufactured	Fenacsone Tab.	Whan In Pharm.	2022-09-22	Antipyretics, analgesics, and anti-inflammatory drugs	Aceclofenac Eperisone hydrochloride
93	Manufactured	Acerisone Tab.	MOTHER'S PHARMACEUTICAL	2022-09-27	Antipyretics, analgesics, and anti-inflammatory drugs	Aceclofenac Eperisone hydrochloride
94	Manufactured	Airfenac Duo Tab.	DongKoo Bio&Pharma Co., Ltd.	2022-09-27	Antipyretics, analgesics, and anti-inflammatory drugs	Aceclofenac Eperisone hydrochloride
95	Manufactured	ADDROZE Tab. 10/2.5 mg	Addpharma	2022-12-21	Antiarteriosclerotic agents	Rosuvastatin calcium Ezetimibe
96	Manufactured	Dunarb Tab. 30/2.5 mg (fimasartan potassium, S-amlodipine)	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-12-27	Antihypertensives	S-amlodipine besylate dihydrate Fimasartan potassium trihydrate
97	Manufactured	Dunarb Tab. 60/2.5 mg (fimasartan potassium, S-amlodipine)	HUTECS KOREA PHARMACEUTICAL CO., LTD.	2022-12-27	Antihypertensives	S-amlodipine besylate dihydrate Fimasartan potassium trihydrate

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
98	Manufactured	Fimadipine Tab. 30/2.5 mg (fimasartan potassium, S-amlodipine)	SHIN POONG PHARM. CO., LTD	2022-12-27	Antihypertensives	S-amlodipine besylate dihydrate Fimasartan potassium trihydrate
99	Manufactured	Fimadipine Tab. 60/2.5 mg (fimasartan potassium, S-amlodipine)	SHIN POONG PHARM. CO., LTD	2022-12-27	Antihypertensives	S-amlodipine besylate dihydrate Fimasartan potassium trihydrate
100	Manufactured	Fimaone-S Tab. 30/2.5 mg (fimasartan potassium, S-amlodipine)	Hana Pharm. Co., Ltd.	2022-12-27	Antihypertensives	S-amlodipine besylate dihydrate Fimasartan potassium trihydrate
101	Manufactured	Fimaone-S Tab. 60/2.5 mg (fimasartan potassium, S-amlodipine)	Hana Pharm. Co., Ltd.	2022-12-27	Antihypertensives	S-amlodipine besylate dihydrate Fimasartan potassium trihydrate

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

Table 36. Drugs Requiring Data Submission with Changes in Strength of Active Ingredients Approved in 2022

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Efficacy/Effectiveness (partially summarized)
1	Imported	Symbicort Rapihaler 80/2.25 microgram	AstraZeneca Korea	2022-01-14	Antitussive expectorants	Treatment of asthma patients
2	Manufactured	Defaxine SR Tab. 25 mg (desvenlafaxine)	Whan In Pharm.	2022-01-28	Psychotropics	Major depression
3	Manufactured	Aminosyn Injection	DAI HAN PHARM CO., LTD.	2022-02-17	Protein and amino acid preparations	Amino acid supplementation for patients for whom oral or gastrointestinal nutrition is impossible, insufficient or contraindicated
4	Manufactured	Aminosynplus Injection	DAI HAN PHARM CO., LTD.	2022-02-17	Protein and amino acid preparations	Amino acid supplementation for patients for whom oral or gastrointestinal nutrition is impossible, insufficient or contraindicated
5	Imported	Rinvoq Extended-release tablet 30 mg (upadacitinib hemihydrate)	AbbVie Korea Ltd.	2022-03-15	Certified therapeutic agents (including non-specific immunosuppressant)	This drug should be used in the following patients only when they do not respond adequately to existing treatment or do not have tolerability. - Applicable Patients - A. Patients aged 65 years or older B. Patients with high cardiovascular risk C. Patients with risk of malignancy 1. Atopic dermatitis Treatment of moderate to severe atopic dermatitis in adults subject to systemic therapy 2. Ulcerative colitis Treatment of moderate to severe active ulcerative colitis in adults who do not respond adequately, have lost their response, or have no tolerability to conventional therapies (treatment with corticosteroid, immunosuppressant, etc.) or biopharmaceuticals
6	Manufactured	Amoburofen Premix Inj. (ibuprofen)	Huons	2022-04-28	Antipyretics, analgesics, and antiinflammatory drugs	Adjuvant therapy with narcotic analgesics for moderate and severe pain control, and antipyretics
7	Manufactured	Preburofen Injection (ibuprofen)	JW Life Science	2022-04-28	Antipyretics, analgesics, and antiinflammatory drugs	Adjuvant therapy with narcotic analgesics for moderate and severe pain control, and antipyretics
8	Manufactured	IBUFEPHEN Inj. (ibuprofen)	JW sinyak	2022-04-28	Antipyretics, analgesics, and antiinflammatory drugs	Adjuvant therapy with narcotic analgesics for moderate and severe pain control, and antipyretics

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Efficacy/Effectiveness (partially summarized)
9	Manufactured	Mirta Tab. 45 mg (mirtazapine)	MYUNG IN PHARM.CO., LTD.	2022-05-11	Psychotropics	Major depression
10	Manufactured	Nebirosta Tab. 2.5/20 mg	Elyson Pharmaceutical Co., Ltd	2022-05-23	Miscellaneous circulatory system drugs	This drug is used as an alternative therapy for combination treatment in patients who are taking both drugs (nebivolol and rosuvastatin) at the same time. ○ Nebivolol 1. Essential hypertension 2. Chronic heart failure (adjuvant treatment for standard treatment in elderly patients aged 70 years or older with mild to moderate chronic stable heart failure) ○ Rosuvastatin 1. Primary hypercholesterolemia (type IIa including heterozygous familial hypercholesterolemia), combined hyperlipidemia (type IIb): Supplements to diet in the case of not being controlled with diet and exercise 2. Supplements to diet or other lipid-lowering therapies (e.g., LDL apheresis) for homozygous familial hypercholesterolemia 3. Delaying the progression of atherosclerosis by lowering total cholesterol and LDL-cholesterol to target levels in patients with hypercholesterolemia 4. Dietary supplement for patients with primary dysbetalipoproteinemia (type III) 5. Reduced risk for cardiovascular disease : Although there is no clinical evidence of coronary heart disease, for patients who are males aged 50 years or older and females aged 60 years or older with a high sensitive C-reactive protein (hsCRP) level of 2 mg/L or higher, and at least one additional cardiovascular disease risk factors (e.g., hypertension, low HDL-cholesterol level, smoking or family history of an early stage coronary heart disease, etc.) - Reduced risk for stroke - Reduced risk for myocardial infarction - Reduced risk for arterial re-vascularization

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Efficacy/Effectiveness (partially summarized)
11	Manufactured	Doxic Tab. 50 mg (doxycycline monohydrate)	Binex	2022-06-30	Acting mainly on gram-positive/negative bacteria, rickettsia, and virus	○ Effective strains: Rickettsia, mycoplasma pneumonia, chlamydia parrot, borrelia recurrentis, granuloma capsular cocci, trachoma chlamydia, haemophilus ducreyi, vibrio cholerae, yersinia pestis, bacteroid, brucella, E. coli, enterobacter, influenza bacillus, klebsiella, streptococcus, streptococcus pneumoniae, staphylococcus aureus, neisseria gonorrhoeae, treponema pallidum, listeria monocytogenes, bacillus anthracis, fusobacterium, francisella tularensis ○ Indication: Typhus, rash fever, caterpillar disease (tsutsugamushi disease), queue fever, Rocky Mountain spotted fever (RMSF), rickettsia, tick fever, mycoplasma pneumonia, pigeon disease, parrot disease, groin granuloma, venereal lymphogranuloma, relapsing fever, chancroid, cholera, plague, Tularemia, brucellosis, syphilis, listeriosis, anthrax, inclusion conjunctivitis, tonsillitis, pharyngitis, bronchitis, bronchiectasis (if infected), pneumonia, lung abscess, mastitis, lymphadenitis, osteomyelitis, scarlet fever, otitis media, sinusitis, gonorrhea, pyelonephritis, cystitis, urethritis, intrauterine infection, acute dacryocystitis, intestinal amoebiasis, trachoma, acne
12	Manufactured	LaminaGchewable tablet 200 mg (sodium alginate)	Taejoon Pharmaceutical Co., Ltd.	2022-07-06	Peptic ulcer drugs	1. Improvement of hemostasis and subjective symptoms of the following diseases: Gastric/duodenal ulcer, erosive gastritis 2. Improvement of subjective symptoms of reflux esophagitis
13	Manufactured	K-CAB Tab. 25 mg (tegoprazan)	HK inno.N corporation	2022-07-20	Peptic ulcer drugs	1. Treatment of erosive gastroesophageal reflux disease 2. Treatment of non-erosive gastroesophageal reflux disease 3. Treatment of gastric ulcer 4. Antibiotic combination therapy for eradication of Helicobacter pylori in patients with peptic ulcer disease and/or chronic atrophic gastritis 5. Maintenance therapy after treatment of erosive gastroesophageal reflux disease <limited to 25 mg>

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Efficacy/Effectiveness (partially summarized)
14	Imported	Olimel N12E	Baxter	2022-08-01	Protein and amino acid preparations	Fluid, electrolyte, amino acid and calorie supplementation for children aged 2 years and older and adult patients who require intravenous nutrition due to impossible, insufficient or limited oral or gastrointestinal nutrition
15	Manufactured	Baropera Injection (peramivir hydrate)	SHIN POONG PHARM. CO., LTD	2022-08-04	Miscellaneous chemotherapeutic agents	Treatment of influenza A or B virus infections in adults and children aged 2 years and older (administration should be started within 48 hours of the onset of the early symptoms of influenza infection.)
16	Manufactured	Fexuclue 10 mg film-coated tablets (fexuprazan HCl)	Daewoong Pharmaceuticals	2022-08-18	Peptic ulcer drugs	1. Treatment of erosive gastro-esophageal reflux disease 2. Improvement of gastric mucosal lesions in acute gastritis and chronic gastritis <limited to 10 mg>
17	Manufactured	VELOXCAB Tab 10 mg (fexuprazan HCl)	iN Therapeutics Co., Ltd.	2022-08-24	Peptic ulcer drugs	1. Treatment of erosive gastro-esophageal reflux disease 2. Improvement of gastric mucosal lesions in acute gastritis and chronic gastritis <limited to 10 mg>
18	Manufactured	ABCITO Tablet 10 mg (fexuprazan HCl)	HANALL BIOPHARMA CO., LTD.	2022-08-24	Peptic ulcer drugs	1. Treatment of erosive gastro-esophageal reflux disease 2. Improvement of gastric mucosal lesions in acute gastritis and chronic gastritis <limited to 10 mg>
19	Manufactured	WECAB Tab.10 mg (fexuprazan HCl)	Daewoong Bio	2022-08-24	Peptic ulcer drugs	1. Treatment of erosive gastro-esophageal reflux disease 2. Improvement of gastric mucosal lesions in acute gastritis and chronic gastritis <limited to 10 mg>
20	Imported	Invega Hafyera (paliperidone palmitate)	Janssen Korea Ltd.	2022-09-22	Psychotropics	Treatment of schizophrenia
21	Imported	Trelegy200Ellipta	GSK Korea	2022-09-26	Miscellaneous respiratory drugs	Maintenance therapy for asthma not adequately controlled by combination therapy of long-acting beta2-agonists and inhaled corticosteroids in adults
22	Imported	Ntense EF Inj.	Fresenius Kabi Korea Ltd.	2022-09-27	Protein and amino acid preparations	Supplementation of calorie, amino acid, essential fatty acid and omega-3 fatty acid for children aged 2 years or older and adults who need jugular vein nutrition due to impossible, insufficient or limited oral or gastrointestinal nutrition

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Efficacy/Effectiveness (partially summarized)
23	Imported	Ntense Inj.	Fresenius Kabi Korea Ltd.	2022-09-27	Protein and amino acid preparations	Supplementation of calorie, amino acid, essential fatty acid and omega-3 fatty acid for children aged 2 years or older and adults who need jugular vein nutrition due to impossible, insufficient or limited oral or gastrointestinal nutrition
24	Manufactured	Lopirol A Tab 100 mg (fenofibric acid)	Alvogen Korea	2022-10-18	Antiarteriosclerotic agents	Treatment of primary hyperlipidemia : hypercholesterolemia (type IIa), combined hypercholesterolemia and hypertriglyceridemia (type IIb), hypertriglyceridemia (type IV)

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Efficacy/Effectiveness (partially summarized)
25	Manufactured	Dexahigh Tab. 4 mg (dexamethasone)	Daewoong Pharmaceuticals	2022-10-31	Adrenal hormonal drugs	1. Endocrine disorders : Primary and secondary adrenocortical insufficiency, acute adrenocortical insufficiency, adrenal genital syndrome 2. Rheumatic disorders Adjuvant therapy for short-term administration to prevent acute progression or exacerbation of the following diseases : Rheumatoid arthritis, polyarthritis, osteoarthritis, acute gouty arthritis, acute and subacute bursitis, epicondylitis, acute nonspecific tenosynovitis 3. Collagenous diseases : Systemic lupus erythematosus, acute rheumatoid carditis, systemic dermatomyositis (polymyositis), scleroderma, rheumatic fever 4. Skin diseases : Pemphigus, severe psoriasis, dermatitis nervosa, edematous sclerosis in adults, lichen, exfoliative dermatitis 5. Allergic diseases : Bronchial asthma, contact dermatitis, atopic dermatitis, serum sickness, seasonal or perennial allergic rhinitis, drug hypersensitivity, urticaria, hay fever, anaphylactic shock 6. Eye diseases : Iritis, iridocyciltis, chorioretinitis, keratitis 7. Gastrointestinal diseases : Ulcerative colitis 8. Blood diseases : Acquired hemolytic anemia, thrombocytopenia 9. Oncological diseases : Leukemia (temporary measure) 10. Edematous disease : Nephrotic syndrome 11. Nervous system disease : Hodgkin's Disease (temporary measure) 12. Others: In case of emergency of severe infection
26	Manufactured	Trenon Soft Cap. 5 mg (isotretinoin)	DongKoo Bio&Pharma Co., Ltd.	2022-10-31	Vitamin A and D preparations	Severe acne (nodular, cystic, or congealing) that does not respond well to other treatments, especially cystic and congealing acne associated with somatic lesions

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Efficacy/Effectiveness (partially summarized)
27	Manufactured	ATMEGCombiGel Soft Capsule 2.5/1000 mg	Korea United Pharm. Inc.	2022-12-01	Antiarteriosclerotic agents	Treatment of combined (IIb) dyslipidemia in which LDL-cholesterol levels are adequately controlled but triglyceride levels are not during atorvastatin monotherapy in adult patients at high risk of coronary heart disease (CHD)
28	Manufactured	Azabio Tab. 12.5 mg (azathioprine)	Pharmbio Korea Inc.	2022-12-21	Certified therapeutic agents (including non-specific immuno suppressant)	Suppression of rejection after kidney transplantation, autoimmune disease
29	Manufactured	Yuhan Pregabalin SR Tablet 75 mg (pregabalin)	YUHAN Coporation	2022-12-30	Miscellaneous central nervous system drugs	Treatment of peripheral neuropathic pain in adults

2.4.4. Drugs with New Route of Administration

There were 2 manufactured items of chemical drugs approved for the new route of administration: a miscellaneous chemotherapeutic agents developed for intramuscular injection and an agent for hair developed as an external spray (refer to Table 37).

Table 37. Drugs Requiring Data Submission with New Route of Administration Approved in 2022

No.	Manufactured/ Imported	Product name	Company	Approval Date	Detailed Classification	Efficacy/Effectiveness (partially summarized)	Route of Administ -ration
1	Imported	REKAMBYS injection (rilpivirine)	Janssen Korea Ltd.	2022-02-03	Miscellaneous chemotherapeutic agents	Combination therapy with cabotegravir injection for the treatment of HIV-1 infection in adult patients who are virologically suppressed (HIV-1 RNA < 50 copies/mL), have no history of treatment failure, and have no known or suspected resistance to rilpivirine or cabotegravir	Oral (tablet) → Muscle (vial)
2	Imported	Finjuve Spray (finasteride)	Boryung Co., Ltd.	2022-09-06	Agents for hair (hair grower, hair loss treatment, hair dye, and hair tonic)	Treatment of mild to moderate male-type alopecia (androgenetic alopecia) in male adults (18 to 41 years old)	Oral (tablet) → External (spray)

2.4.5. Drugs with New Mode of Administration/Dosage

3 items of chemical drugs (2 manufactured items, 1 imported item) were approved for new mode of administration and dosage: 1 item of iron preparation developed for injection with new mode of administration and dosage to supply iron to renal failure patients undergoing hemodialysis, and 2 items approved by convergence of collagen-using tissue supplement and anti-adhesion coating device, that are medical devices, with thrombin lyophilized powder, respectively (refer to Table 38).

Table 38. Drugs Requiring Data Submission with New Administration/Dosage Approved in 2022

No.	Manufactured/ Imported	Product name	Company	Approval Date	Detailed Classification	Efficacy/Effectiveness (partially omitted)
1	Imported	Triferic injection (ferric pyrophosphate citrate sodium sulfate coprecipitate hydrate)	JEIL PHARMACEUTICAL CO., LTD.	2022-01-11	Mineral preparations	1. Dosage The recommended dosage of the drug is 6.75mg of undiluted iron(III) as a slow continuous intravenous infusion over 3 to 4 hours via a pre-dialysis infusion line, a post-dialysis infusion line, or a separate line connected to the venous line of the dialysis machine... -Hereinafter omitted- 2. Mode of Administration Patients should be closely monitored for signs and symptoms of hypersensitivity during and after every administration of this drug. -Hereinafter omitted-

No.	Manufactured/ Imported	Product name	Company	Approval Date	Detailed Classification	Efficacy/Effectiveness (partially omitted)
2	Manufactured	HemoShield Hemostatic (thrombin)	BMI KOREA	2022-04-20	Hemostatics	1. Thrombin lyophilized powder 5000 units (thrombin) Usually, a solution dissolved in physiological saline (50 to 1,000 units/mL as thrombin) is sprayed, tube-injected, or dispersed as powder in itself on the site of local bleeding. Increase or decrease appropriately depending on the site and degree of bleeding. 2. Collagen-using tissue supplement device (1) Preparation before use 1) Before use, check that the container of the product is not damaged. -Hereinafter omitted-
3	Manufactured	Qfence Hemostatic (thrombin)	BMI KOREA	2022-04-20	Hemostatics	1. Thrombin lyophilized powder 5000 units (thrombin) Usually, a solution dissolved in physiological saline (50 to 1,000 units/mL as thrombin) is sprayed, tube-injected, or dispersed as powder in itself on the site of local bleeding. Increase or decrease appropriately depending on the site and degree of bleeding. 2. Anti-adhesion coating device A. Preparation before use (1) Be careful not to open the package until just before use. (2) When using the device, the packaging must be opened in a sterilized place. -Hereinafter omitted-

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

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

30 items of chemical drugs were approved for the new dosage form (same route of administration) (24 manufactured items and 6 imported items). Analyzing the types of development, the approved items include: 7 items (23.3%) developed from capsules into film-coated tablets, 4 items (13.3%) developed from tablets into orally disintegrating tablets, and 4 items (13.3%) developed from tablets into liquids for internal use and from vials into pre-filled syringes, 2 items (6.7%) developed from sustained-release capsules into sustained-release tablets, 2 items (6.7%) developed from ampules into vials, and existing capsule developed into tablet, tablet into suspension, lyophilized powder into liquid injection, oral liquid into tablet, and cream into gel were approved (refer to Table 39).

Table 39. Drugs Requiring Data Submission with New Dosage Form (Same Route of Administration) Approved in 2022

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	New Formulation
1	Imported	NALADOR Vial Inj. 500 (sulprostone)	Bayer Korea Ltd.	2022-01-20	Uterine contraction drugs	Ampule → Vial
2	Manufactured	K-CAB ODT 50 mg (tegoprazan)	HK inno.N corporation	2022-02-09	Peptic ulcer drugs	Tablet → Orally disintegrating tablet
3	Manufactured	BrisTurn Prefilled Inj. (sugammadex sodium)	LitePharmTech Co., Ltd.	2022-02-14	Autonomic nervous system drugs	Vial → Pre-filled syringe
4	Manufactured	Sugadion Prefilled Inj. (sugammadex sodium)	Hyundai Pharm Co., Ltd.	2022-02-14	Autonomic nervous system drugs	Vial → Pre-filled syringe
5	Manufactured	Yooridion inj. (sugammadex sodium)	YooYoung Pharmaceutical Co., Ltd	2022-02-14	Autonomic nervous system drugs	Vial → Pre-filled syringe
6	Manufactured	ILSUNG Sugammadex Sodium Inj	ILsung Pharmaceuticals Co., Ltd.	2022-02-14	Autonomic nervous system drugs	Vial → Pre-filled syringe

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	New Formulation
7	Imported	IBRANCE Tablet 100 mg (palbociclib)	Pfizer Korea Ltd.	2022-02-14	Anti-tumor agents	Capsule → Tablet
8	Imported	IBRANCE Tablet 125 mg (palbociclib)				
9	Imported	IBRANCE Tablet 75 mg (palbociclib)				
10	Manufactured	Hypezil powder 5 mg (donepezil hydrochloride hydrate), Hypezil powder 10 mg (donepezil hydrochloride hydrate)	Hyundai Pharm Co., Ltd.	2022-04-11	Miscellaneous central nervous system drugs	Tablet → Orally disintegrating tablet
11	Imported	Teglutik Oral Suspension (riluzole)	SK Chemicals	2022-05-31	Miscellaneous central nervous system drugs	Tablet → Suspension
12	Manufactured	Famofang OD Tab. 10 mg (famotidine)	Pharmbio Korea Inc.	2022-06-09	Peptic ulcer drugs	Tablet → Orally disintegrating tablet
13	Manufactured	Pharmbio Korea Famotidine OD Tablet 10 mg	Pharmbio Korea Inc.	2022-06-09	Peptic ulcer drugs	Tablet → Orally disintegrating tablet
14	Manufactured	Dilatrend SR Tab 32 mg (carvedilol)	Chong Kun Dang Pharm.	2022-06-28	Antihypertensives	SR capsule → SR tablet
15	Manufactured	Dilatrend SR Tab 64 mg (carvedilol)	Chong Kun Dang Pharm.	2022-06-28	Antihypertensives	SR capsule → SR tablet
16	Manufactured	K-CEPT Oral Solution 5 mg, 10 mg (donepezil hydrochloride hydrate)	GENUONE Sciences Inc.	2022-07-15	Miscellaneous central nervous system drugs	Tablet → Oral liquid
17	Manufactured	BEARCEPT Soln. 5 mg, 10 mg (donepezil hydrochloride hydrate)	Daewoong Bio	2022-07-18	Miscellaneous central nervous system drugs	Tablet → Oral liquid
18	Manufactured	Sinsin Donepezil Solution 5 mg, 10 mg (donepezil hydrochloride hydrate)	SINSIN Pharmaceutical Co., Ltd.	2022-07-18	Miscellaneous central nervous system drugs	Tablet → Oral liquid
19	Manufactured	JW Donepezil Sol. 5 mg, 10 mg (donepezil hydrochloride hydrate)	JW Pharmaceutical	2022-07-18	Miscellaneous central nervous system drugs	Tablet → Oral liquid
20	Manufactured	Gaster Inj. 20 mg (famotidine)	DONG-A ST	2022-08-11	Peptic ulcer drugs	Lyophilized powder → Liquid injection
21	Manufactured	Zerofat Tab. 120 mg (orlistat)	MOTHER'S PHARMACEUTICAL	2022-11-16	Miscellaneous metabolic drugs	Capsule → Film-coated tablet

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	New Formulation
22	Manufactured	Light-Slim Tab. 120 mg (orlistat)	Hana Pharm. Co., Ltd.	2022-11-18	Miscellaneous metabolic drugs	Capsule → Film-coated tablet
23	Manufactured	Olistat Tab. 120 mg (orlistat)	DAEHWA Pharm	2022-11-18	Miscellaneous metabolic drugs	Capsule → Film-coated tablet
24	Manufactured	Orlyone tab. 120 mg (orlistat)	CMG Pharmaceutical Co., Ltd	2022-11-18	Miscellaneous metabolic drugs	Capsule → Film-coated tablet
25	Manufactured	Zero-be Tab. 120 mg (orlistat)	Daehan New Pharm	2022-11-18	Miscellaneous metabolic drugs	Capsule → Film-coated tablet
26	Manufactured	Zerowon Tab. 120 mg (orlistat)	WONKWANG PHARMACEUTICAL CORPORATION	2022-11-18	Miscellaneous metabolic drugs	Capsule → Film-coated tablet
27	Manufactured	Citria Tab (citrulline malate)	KIMS Pharmaceutical Co., Ltd.	2022-12-27	Miscellaneous metabolic drugs	Oral liquid → Tablet
28	Imported	Blissel Gel (estriol)	NK MEDITECH	2022-12-30	Urogenital drugs (including venereal disease preventives)	Cream → Gel
29	Manufactured	Amonosin-A Inj. (adenosine triphosphate disodium trihydrate)	Huons	2022-12-28	Miscellaneous metabolic drugs	Ampule → Vial
30	Manufactured	Zerofat Tab. 60 mg (orlistat)	MOTHER'S PHARMACEUTICAL	2022-12-28	Miscellaneous metabolic drugs	Capsule → Film-coated tablet

※ Detailed approval information (efficacy/effectiveness, dosage/mode of administration, 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 biopharmaceutical products) in 2022 by review type, there were 10 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 3 orphan drugs (excluding 4 new orphan drugs) (refer to Table 40). More specifically, 22 biopharmaceuticals and 31 recombinant protein products were approved (refer to Table 41).

Table 40. Biologics Approved in 2022 by Review Type (Including Advanced Biopharmaceutical Products)

<Including Drugs for Export and Drug Substances>

<table>
<tr><th>Type</th><th colspan="3">Review Type</th><th>Number of Approved Items</th></tr>
<tr><td>1</td><td rowspan="2">New Drugs (10)</td><td colspan="2">New Drugs</td><td>6</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">New Orphan Drugs</td><td rowspan="2">Orphan Drugs (7)</td><td>4</td></tr>
<tr><td>3</td><td colspan="2">Orphan Drugs</td><td>3</td></tr>
<tr><td>4</td><td colspan="3">Drugs requiring data submission</td><td>40</td></tr>
<tr><td>4-1</td><td colspan="3">Incrementally modified drugs</td><td>0</td></tr>
<tr><td>4-2</td><td rowspan="2">Drugs requiring data submission</td><td colspan="2">Biosimilar products</td><td>7</td></tr>
<tr><td>4-3</td><td colspan="2">Other drugs requiring data submission</td><td>33</td></tr>
<tr><td colspan="4">Total</td><td>53</td></tr>
</table>

<Excluding Drugs for Export and Drug Substances>

<table>
<tr><th>Type</th><th colspan="3">Review Type</th><th>Number of Approved Items</th></tr>
<tr><td>1</td><td rowspan="2">New Drugs
(10)</td><td colspan="2">New Drugs</td><td>6</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">New Orphan Drugs</td><td rowspan="2">Orphan Drugs
(7)</td><td>4</td></tr>
<tr><td>3</td><td colspan="2">Orphan Drugs</td><td>3</td></tr>
<tr><td>4</td><td colspan="3">Drugs requiring data submission</td><td>36</td></tr>
<tr><td>4-1</td><td colspan="3">Incrementally modified drugs</td><td>0</td></tr>
<tr><td>4-2</td><td rowspan="2">Drugs requiring data submission</td><td colspan="2">Biosimilar products</td><td>7</td></tr>
<tr><td>4-3</td><td colspan="2">Other drugs requiring data submission</td><td>29</td></tr>
<tr><td colspan="4">Total</td><td>49</td></tr>
</table>

Table 41. Biologics Approved in 2022 (Including Advanced Biopharmaceutical Products)

<Including Drugs for Export and Drug Substances>

Type	Total	Number of Approved Items		Remarks
		Manufactured	Imported	
Total	53	20	33	
Biopharmaceuticals	22	12	10	New drugs (4), Drugs requiring data submission (18, including drugs for export (3), substance (1))
Recombinant Protein Products	31	8	23	New drugs (6), Orphan drugs (3, excluding new orphan drug), Drugs requiring data submission (22)
Advanced Biopharmaceutical Products	0	0	0	-

<Excluding Drugs for Export and Drug Substances>

Type	Total	Number of Approved Items		Remarks
		Manufactured	Imported	
Total	49	16	33	
Biopharmaceuticals	18	8	10	New drugs (4), Drugs requiring data submission (14)
Recombinant Protein Products	31	8	23	New drugs (6), Orphan drugs (3, excluding new orphan drug), Drugs requiring data submission (22)
Advanced Biopharmaceutical Products	0	0	0	-

3.1. Approval Status of Biopharmaceuticals

22 biopharmaceuticals were approved in 2022 (12 manufactured items, 10 imported items, 14 vaccines, 3 botulinum toxins, and 5 blood products).

By comparison, 15 items (10 manufactured items, 5 imported items, 8 vaccines, 7 botulinum toxins) were approved in 2021 and 20 items (18 manufactured items, 2 imported items, 9 vaccines, 7 botulinum toxins, 4 blood products) were approved in 2020. It is indicative of the decline in the number of biopharmaceuticals approvals observed since 2020. But in 2022, that of approvals slightly increased.

Vaccines approved in 2022 include 8 coronavirus infection-19 (hereinafter referred to as COVID-19) vaccines, 1 typhoid vaccine, 1 meningococcal vaccine, 1 influenza vaccine, and 2 combination vaccines (refer to Table 42).

As for COVID-19 vaccines, 2 recombinant vaccines and 6 mRNA vaccines were approved. A recombinant vaccine is produced from directly inserting an antigen protein produced by recombinant technology, which stimulates the production of antibodies that can fight the virus in the body. A mRNA vaccine is produced from injecting the surface antigen gene of the COVID-19 virus in the form of mRNA, which synthesizes antigen proteins in the body, and induces the production of neutralizing antibodies, thereby neutralizing and eliminating the virus when it invades the human body.

As for the recombinant vaccine, a manufactured and marketed item **"NUVAXOVID Pre-filled Syringe (SARS-CoV-2 Spike Protein Vaccine (recombinant))"** which was developed by Novavax and produced by SK

bioscience Co., Ltd., and a manufactured and marketed item **“SkyCovione Multi Injection (SARS-CoV-2 surface antigen vaccine (recombinant)),”** which was developed and produced by SK bioscience Co., Ltd, were approved as a domestically manufactured new drug and a domestically developed new drug, respectively.

Among the mRNA vaccines, 3 items were imported items of Pfizer Korea Ltd., which were **“Comirnaty Inj. 0.1 mg/mL (tozinameran) (SARS-CoV-2 mRNA vaccine),”** **“Comirnaty Inj. 0.1 mg/mL (5-11 Years) (tozinameran) (SARS-CoV-2 mRNA vaccine)”** targeting children aged 5-11 years old, and **“Comirnaty Inj. 0.1 mg/mL (6 Months - 4 Years) (tozinameran) (SARS-CoV-2 mRNA vaccine)”** targeting children aged 6 months to 4 years old, and all of which were drugs requiring data submission.

Among the mRNA vaccines, the remaining 3 items approved are as follows: an imported item, **“Comirnaty 2 Injection 0.1mg/mL (tozinameran, riltozinameran)”** of Pfizer Korea Ltd., as a bivalent vaccine for COVID-19 that expresses each antigen of the early COVID-19 virus and the mutant virus (Omicron variant BA.1), “MODERNA SPIKEVAX BIVALENT (Elasomeran, Imelasomeran) (SARS-CoV-2 mRNA vaccine), a imported item, and **“SPIKEVAX BIVALENT (Elasomeran, Imelasomeran) (SARS-CoV-2 mRNA vaccine)”** , a manufactured and marketed item, of Moderna Korea, all of which were drugs requiring data submission.

The GSK Korea’s **“Bexsero”** as a meningococcal vaccine and a new drug, was approved for the prevention of invasive meningococcal disease caused by Neisseria meningitidis group B in children aged 2 months or older.

The MEDITIP’s **“Fluad® Quad Prefilled Syringe”** as both an influenza vaccine and an imported item was approved, which is a preventive vaccine

for influenza diseases caused by influenza A viruses and influenza B viruses contained in this vaccine in the elderly aged 65 years or older.

As a combination vaccine, Sanofi Pasteur's **"Adacel Pre-filled Syringe (adsorbed diphtheria, tetanus toxoid and purified pertussis combined vaccine for adults)"** as an imported item was approved, which is used for the prevention of diphtheria, tetanus and pertussis. In addition, Boryeong Biopharma's **"Boryeong TD Vaccine Pre-filled Syringe (adsorbed diphtheria and tetanus combination vaccine for adults),"** as a manufactured and marketed item was approved for the prevention of diphtheria and tetanus.

As a typhoid vaccine, SK Bioscience Co., Ltd.'s **"SKYTyphoid multi inj. (Thyphoid purified Vi Polysaccharide Conjugated to Diphtheria toxoid vaccine)"** was approved.

In the case of botulinum toxin products, 4 items were newly approved in 2016, 2 items in 2017, 1 item in 2018, and 2 items (1 item for domestic use and 1 item for export) in 2019, and 7 items for export in 2020, 7 items (6 items for domestic use, 1 item for export) in 2021, and 3 items (1 item for domestic use, 2 items for export) in 2022 (refer to Table 42).

Among the botulinum toxin products approved in 2022, **"ATOXIN Inj."** from Daewoong Bio Inc. was approved for the temporary improvement of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged between 20 and 65 years and the treatment of upper extremity spasticity associated with stroke in adults aged 18 years and older.

"TYEMVERS for injection(Clostridium botulinum Toxin Type A)(for export)" from CKD BiO was approved for temporarily improving moderate

to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged between 19 and 65 years. **“BOTAONE Inj.(Clostridium botulinum Toxin Type A)(For export only)”** from GENETOX was approved together with the approved purpose thereof, for temporarily improving ocular wrinkles (wrinkle around the eye) in moderate to severe cases associated with orbicularis oculi muscle activity in adults aged 19 to 65 years of age,

In the case of blood products, 2 items were approved in 2017 and 1 item was approved in 2018, but there were no newly approved items from 2019 to 2020. And 4 items were approved in 2021 and 5 items were approved in 2022 (refer to Table 40).

The Ministry of Food and Drug Safety operated the “Our Own Vaccine Project” to provide intensive and systematic support so that domestic COVID-19 vaccines could be developed quickly amid the COVID-19 situation. As a result, the COVID-19 vaccine developed and manufactured by a Korean company was approved for the first time in the world.

In addition, Vaccine Center for Assisting Safety &Technology was established to make efforts to preemptively respond to future infectious diseases by providing technical support for commercialization of drug development companies, such as basic consultation on vaccine development, quality and clinical trials, etc.

Table 42. List of Approved Biopharmaceuticals in 2022

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/ Effectiveness (partially summarized)	Remarks
1	Manufactured	NUVAXOVID Pre-filled Syringe (SARS-CoV-2 surface antigen vaccine (recombinant))	SARS-CoV-2 spike protein (recombinant) (Host: Sf9, Vector: BV2373)	SK bioscience Co., Ltd.	2022-01-12	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older	New drugs
2	Imported	Bexsero	Recombinant meningococcal group B NHBA fusion protein, recombinant meningococcal group B NadA protein, recombinant meningococcal group B fHBP fusion protein, meningococcal group B strain NZ98/254 outer membrane vesicle	GSK Korea	2022-05-19	Prevention of invasive meningococcal disease caused by Neisseria meningitidis group B in children aged 2 months or older	New drugs
3	Manufactured	SkyCovione Multi Injection (SARS-CoV-2 surface antigen vaccine (recombinant))	SARS-CoV-2 spike protein RBD antigen (recombinant) (Host 1:CHO-K1(HD-BICP3), Vector 1: M-2560, Host 2: E.coli(BL21), Vector 2: pET296(+))	SK bioscience Co., Ltd.	2022-06-29	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older	New drugs
4	Imported	Ceprotin Inj. (human protein C)	Human protein C	Takeda Pharmaceuticals Korea Co., Ltd.	2022-08-02	Prevention and treatment of venous thrombosis and purpura fulmina in pediatric and adult patients with severe congenital protein C deficiency	New orphan drugs
5	Imported	Comirnaty Injection 0.1 mg/mL (tozinameran) (SARS-CoV-2 virus mRNA vaccine)	SARS-CoV-2 spike protein expression messenger ribonucleic acid (tozinameran) (Host: DH10B, Vector: pST4-1525)	Pfizer Korea Ltd.	2022-01-28	Prevention of COVID-19 caused by SARS-CoV-2 virus in 12 years of age or older	Drugs requiring data submission
6	Imported	Comirnaty Injection 0.1 mg/mL (5-11	SARS-CoV-2 spike protein expression	Pfizer Korea Ltd.	2022-02-23	Prevention of COVID-19 caused by SARS-CoV-2 virus in	Drugs requiring data

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/ Effectiveness (partially summarized)	Remarks
		Years) (tozinameran) (SARS-CoV-2 mRNA vaccine)	messenger ribonucleic acid (tozinameran) (Host: DH10B, Vector: pST4-1525)			5 to 11 years of age	submission
7	Manufactured	Washed platelets from Busan Blood Center, Korean Red Cross (washed platelet)	Washed platelet	Busan Blood Center, Korean Red Cross	2022-07-06	1. Prevention or treatment of bleeding in patients with thrombocytopenia or platelet dysfunction 2. Used for patients with a history of transfusion side effects caused by plasma proteins after transfusion such as urticaria, allergic reactions, anaphylaxis, etc.	Drugs requiring data submission
8	Manufactured	Liv gamma SN Inj.	Human immunoglobulin-G	SK Plasma	2022-08-22	1. Low and agammaglobuline mia 2. Combined use of antibiotics for severe infections 3. Idiopathic thrombocytopenic purpura 4. Guillain-Barre syndrome 5. Kawasaki disease	Drugs requiring data submission
9		Washed platelets from Daejeon Sejong Chungnam Blood Center, Korean Red Cross (washed platelet)	Washed platelet	Daejeon Sejong Chungnam Blood Center, Korean Red Cross	2022-08-22	1. Prevention or treatment of bleeding in patients with thrombocytopenia or platelet dysfunction 2. Used for patients with a history of transfusion side effects caused by plasma proteins after transfusion such as urticaria, allergic reactions, anaphylaxis, etc.	Drugs requiring data submission
10	Imported	MODERNA SPIKEVAX BIVALENT (Elasomeran,	SARS-CoV-2 spike protein expressing messenger ribonucleic acid (elasomeran)	Moderna Korea Co., Ltd.	2022-09-08	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of	Drugs requiring data submission

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/ Effectiveness (partially summarized)	Remarks
		Imelasomeran) (SARS-CoV-2 mRNA vaccine)	(Host: DIG315, Vector: PL-022856), SARS-CoV-2 spike protein expressing messenger ribonucleic acid (imelasomeran) (Host: DIG315, Vector: PL-028 274)			age or older	
11	Imported	Fluad® Quad Prefilled Syringe)	Purified inactivated influenza virus antigen type A [A/California/7/2009 Reassortant virus NYMC-X181 (H1N1)], purified inactivated influenza virus antigen type A (A/Hong Kong/ 4801/2014, H3 N2, NYMC X-263B), purified inactivated influenza virus antigen type B (B/Brisbane /9/2014, wild type), purified inactivated influenza virus antigen type B (B/Brisbane /60/2008)	MEDITIP	2022-09-19	Prevention of influenza disease caused by influenza A viruses and influenza B viruses contained in the vaccine in the elderly aged 65 years or older	Drugs requiring data submission
12	Imported	Verasil Pre-filled Syringe Kit	Human fibrinogen	Johnson & Johnson Medical Korea Ltd.	2022-09-27	Assistance to hemostasis in adult patients undergoing surgery when control of bleeding is insufficient with standard surgical techniques (suturing, ligation, or cauterization, etc.) - hemostasis improvement - Suture assistance in vascular surgery	Drugs requiring data submission
13	Manufactured	SPIKEVAX BIVALENT (Elasomeran, Imelasomeran) (SARS-CoV-2 mRNA vaccine)	SARS-CoV-2 spike protein expressing messenger ribonucleic acid (elasomeran) (Host: DIG315, Vector: PL-022856), SARS-CoV-2 spike protein expressing messenger	Moderna Korea Co., Ltd.	2022-10-07	Prevention of COVID-19 caused by SARS-CoV-2 virus in 18 years of age or older	Drugs requiring data submission

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/ Effectiveness (partially summarized)	Remarks
			ribonucleic acid (imelasomeran) (Host: DIG315, Vector: PL-028274)				
14	Imported	Comirnaty 2 Injection 0.1mg/mL (tozinameran, riltozinameran) (SARS-CoV-2 mRNA vaccine)	SARS-CoV-2 spike protein expression messenger ribonucleic acid (tozinameran) (Host: DH10B, Vector: pST4-1525), SARS-CoV-2 spike protein expression messenger ribonucleic acid(riltozinameran) (Host: DH10B, Vector: pST4-1857)	Pfizer Korea Ltd.	2022-10-07	Prevention of COVID-19 caused by SARS-CoV-2 virus in 12 years of age or older	Drugs requiring data submission
15	Imported	Adacel Pre-filled Syringe (adsorbed diphtheria, tetanus toxoid and purified pertussis combination vaccine for adults)	Diphtheria toxoid (Strain name: C.diphtheriae L34T1 strain), tetanus toxoid (Strain: C.tetani Boston II 60 strain), pertussis toxoid (Strain: B. Pertussis 10536 strain), FHA (Strain: B. Pertussis 10536 strain), FIM 2+3 (Strain: B. Pertussis 10536 strain), PRN (Strain: B. Pertussis 10536 strain)	Sanofi Pasteur	2022-11-11	Prevention of diphtheria, tetanus and pertussis	Drugs requiring data submission
16	Manufactured	Boryung Co., Ltd. TD Vaccine Pre-filled Syringe	Diphtheria toxoid (Strain: Diphtheria bacteria Park-Williams No.8 strain), tetanus toxoid(Strain: Tetanus Harvard strain)	Boryung Co., Ltd. Biopharma	2022-11-14	Prevention of Diphtheria and tetanus	Drugs requiring data submission
17	Imported	Comirnaty Injection 0.1	SARS-CoV-2 spike protein	Pfizer Korea Ltd.	2022-11-25	Prevention of COVID-19 caused	Drugs requiring data

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/ Effectiveness (partially summarized)	Remarks
		mg/mL (6 Months - 4 Years) (tozinameran) (SARS-CoV-2 mRNA vaccine)	expression messenger ribonucleic acid (tozinameran) (Host: DH10B, Vector: pST4-1525)			by SARS-CoV-2 virus in 6 months to 4 years of age	submission
18	Manufactured	ATOXIN Inj.	Clostridium Botulinum Toxin Type A	Daewoong Bio	2022-09-01	1. Temporary improvement of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged between 20 and 65 2. Muscular stiffness: Treatment of upper extremity spasticity associated with stroke in adults aged 18 years and older	Drugs requiring data submission
19	Manufactured	TYEMVERS for injection(Clostridium botulinum Toxin Type A)(for export)	Clostridium Botulinum Toxin Type A	CKD BiO Corp.	2022-02-09	Temporary improvement of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged between 19 and 65	For export
20	Manufactured	BOTAONE Inj.(Clostridium botulinum Toxin Type A)(For export only)	Clostridium Botulinum Toxin Type A	GENETOX	2022-10-27	1. Temporary improvement of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activities in adults aged between 18 and 65 2. Temporary improvement of ocular wrinkles (wrinkle around the eye) in moderate to severe cases	For export

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/ Effectiveness (partially summarized)	Remarks
						associated with orbicularis oculi muscle activity in adults aged 19 to 65 years of age	
21	Manufactured	SKYTyphoid multi inj. (Thyphoid purified Vi Polysaccharide Conjugated to Diphtheria toxoid vaccine)	Purified Vi polysaccharide (strain: S.Typhi C6524)-diphtheria toxoid (Strain: C. diphtheriae) conjugate	SK bioscience Co., Ltd.	2022-05-12	Prevention of diseases caused by Salmonella typhi in children 6 months of age or older and adults 45 years of age or younger	For export
22	Manufactured	EUBIOLOGICS Vi Polysaccharide Stock Solution (for export)	Vi polysaccharide	EUBIOLOGICS	2022-03-11	For manufacturing typhoid vaccine	Stock solution, for export

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

3.2. Approval Status of Recombinant Protein Products

A total of 31 recombinant protein products were newly approved in 2022 (8 manufactured items and 23 imported items) including 6 new drugs (including new orphan drugs) and 6 orphan drugs (excluding 3 new orphan drugs), and 22 drugs requiring data submission (refer to Table 43).

In 2022, 5 ingredients and 6 items were designated as new drugs (including new orphan drugs) while new drugs approved in 2021 were 4 ingredients and 5 items, which showed the increase in the number of new drug approvals in 2022. 5 ingredients and 6 items were approved as orphan drugs (excluding new orphan drugs) in 2022, which showed the increase compared to 4 ingredients and 4 items approved in 2021.

“Ozempic Pre-filled Pen (semaglutide)” (Novo Nordisk Pharma Korea, Ltd., 2022.04.28.), as a glucagon-like peptide-1 (GLP-1) receptor agonist,

was approved as a new drug that has been improved to be administered once a week by increasing a half-life compared to the previously approved Victoza Pen Inj. (liraglutide). It is administered as an adjunct to diet and exercise therapy in adults with insufficient control of type 2 diabetes.

“Reblozyl Injection 25 mg(Luspatercept),” and **“Reblozyl Injection 75 mg(Luspatercept)”** (BMS Pharmaceutical Korea Ltd., 2022.5.9) were approved as new orphan drugs used for the treatment of anemic adult patients (beta thalassemia, myelodysplastic anemia). These drugs act on endogenous inhibitors of late erythropoiesis to increase the release of mature erythrocytes into the circulatory system.

“Enhertu Inj. 100 mg (Trastuzumab Deruxtecan)” (Daiichi Sankyo Korea Co., Ltd., 2022.9.19) was approved as a new drug for the treatment of HER2-positive breast cancer and HER2-positive gastric cancer. This drug is an antibody drug conjugate (ADC) in which a humanized monoclonal antibody targeting HER2 and a topoisomerase 1 inhibitor are linked in a conjugate, the antibody (Trastuzumab) specifically targets HER2-expressing tumors, and a drug (Deruxtecan) inhibits cell proliferation and induces tumor cell death.

“Poteligeo injection 20 mg (Mogamulizumab)” (Kyowa Kirin Korea Co., Ltd, 2022.9.22) was approved as a new orphan drug for the treatment of adult patients with mycosis fungoides or Sézary syndrome who previously received one or more systemic therapies. Mogamulizumab, the active ingredient, induces antibody-dependent cellular cytotoxicity (ADCC) activity that kills cancer cells by selectively binding to CCR4 expressed on the surface of cancer cells.

“Jemperli Inj. (dostarlimab)” (GSK Korea, 2022.12.14) was approved as a new drug for the treatment of adult patients who have recurrent or progressive mismatch repair deficient (dMMR)/high frequency microsatellite instability-high (MSI-H) endometrial cancer. As a monoclonal antibody targeting PD-1, immune checkpoint receptor of T cells, the drug blocks cancer cells from using the PD-1 pathway to suppress cell activation, thereby maintaining T-cell immune function.

“Rybrevant Injection (amivantamab)” (Janssen Korea Ltd., 2022.2.15) is an orphan drug for the treatment of patients with locally advanced or metastatic non-small cell lung cancer with an epidermal growth factor receptor (EGFR) exon 20 insertion mutation that has progressed during or after platinum-based chemotherapy treatment. Amivantamab is an EGFR-MET bispecific antibody that targets the EGFR and mesenchymal epithelial transition (MET) pathways concurrently.

“Libtayo Injection (cemiplimab)” (Sanofi-aventis Korea, 2022.10.25.) is an immuno-anticancer agent that binds specifically to the programmed cell death 1 (PD-1) protein and blocks its interaction with the programmed death protein ligand 1 (PD-L1) and death protein ligand 2 (PD-L2). It was approved as an orphan drug for use in locally advanced or metastatic squamous cell carcinoma of the skin that is non-subject to curative surgery or curative radiation therapy.

“Ultomiris Inj. 100 mg/mL (ravulizumab)” (Handok Inc., 2022.12.28) is a product with increased concentration (10 mg/mL → 100 mg/mL) compared to the previously approved item, **“Ultomiris Inj. (ravulizumab)”** (approved on 2020.05.21.), and was approved as an orphan drug used for the same

efficacy and effectiveness (paroxysmal nocturnal hemoglobinuria, atypical hemolytic uremic syndrome).

For biosimilars, 3 ingredients and 7 items were approved. Since the approval of the monoclonal antibody biosimilar drug in 2012 for the first time in the world, a total of 25 types and 42 items were approved until 2022. Out of them, there are a total of 17 types and 30 items of biosimilar products developed in Korea (refer to Table 44).

“Alymsys Injection (bevacizumab)” (Alvogen Korea, 2022.1.19.) is a biosimilar drug developed with Roche Korea’s Avastin Inj. (Bevacizumab) as a reference product.

“AMELIVU” (Samsung Bioepis, 2022.5.13.) and **“Chong Kun Dang Ranibizumab inj.”** (Chong Kun Dang Pharm., 2022.10.20.) are biosimilar drugs developed in Korea with Novartis Korea’s Lucentis Inj. 10 mg/mL (ranibizumab, recombinant) as a reference product.

“Vegzelma” (Celltrion, 2022.9.28.) is a biosimilar drug developed in Korea with Roche Korea’s Avastin Inj. (bevacizumab) as a reference product.

“Yuflyma Pre-filled Syringe Inj. 80 mg/0.8 mL (adalimumab, recombinant),” “Yuflyma Pen Inj. 80 mg/0.8 mL (adalimumab, recombinant),” “Celltrion Yuflyma Pen Inj. 40 mg/0.4 mL (adalimumab, recombinant)” (Celltrion, 2022.6.15./2022.11.10) are biosimilar drugs developed in Korea with AbbVie Korea’s Humira 80 mg/0.8 mL (Adalimumab) and Humira 40 mg/0.4 mL (Adalimumab) as reference products.

Table 43. List of Approved Recombinant Protein Products in 2022

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/Effectiveness (partially summarized)	Remarks
1	Imported	Ozempic Prefilled Pen	Semaglutide	Novo Nordisk Pharma Korea, Ltd.	2022-04-28	- Adjuvant drug for diet and exercise therapy in adults with insufficient - Reduced risk of major control of type 2 diabetes. cardiovascular events in adult patients with type 2 diabetes and confirmed cardiovascular disease	New drugs
2	Imported	Reblozyl Injection 25 mg	Luspatercept	BMS Pharmaceutical Korea Ltd.	2022-05-09	1. Treatment of adult patients with anemia who require red blood cell transfusion due to an inadequate response to or unsuitable for erythropoiesis-stimulating agent (ESA) therapy 2. Treatment of beta thalassemia in adult patients requiring red blood cell transfusion	New orphan drugs
3	Imported	Reblozyl Injection 75 mg					New orphan drugs
4	Imported	Enhertu Inj. 100 mg	Trastuzumab deruxtecan	Daiichi Sankyo Korea Co., Ltd.	2022-09-19	1. Treatment of patients with unresectable or metastatic HER2-positive breast cancer who have previously received two or more anti-HER2-based treatments 2. Treatment of locally advanced or metastatic HER2-positive gastric or gastro esophageal junction adenocarcinoma who have previously received two or more treatments, including anti-HER2 treatment	New drugs
5	Imported	Poteligeo Injection 20 mg	Mogamulizumab	Kyowa Kirin Korea Co., Ltd	2022-09-22	Treatment of adult patients with Mycosis Fungoides or Sézary syndrome who have previously received one or more systemic therapy	New orphan drugs
6	Imported	Jemperli Injection	Dostarlimab	GSK Korea	2022-12-14	Treatment of adult patients with recurrent or progressive mismatch repair deficient (dMMR)/high frequency micro satellite instability-high (MSI-H) endometrial cancer who have progressed during or after treatment with prior platinum-based systemic chemotherapy	New drugs
7	Imported	Rybrevant Injection	Amivantamab	Janssen Korea Ltd.	2022-02-15	Treatment of patients with locally advanced or metastatic non-small cell lung cancer with an epidermal growth factor	Orphan drugs

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/Effectiveness (partially summarized)	Remarks
						receptor (EGFR) exon 20 insertion mutation that has progressed during or after platinum-based chemotherapy treatment	
8	Imported	Libtayo Injection	Cemiplimab	Sanofi-aventis Korea Co., Ltd.	2022-10-25	Locally advanced or metastatic squamous cell carcinoma of the skin that is non-subject to curative surgery or curative radiation therapy.	Orphan drugs
9	Imported	Ultomiris Inj.	Ravulizumab	Handok Inc.	2022-12-28	1. Treatment of paroxysmal nocturnal hemoglobinuria (PNH) in adults 2. Treatment of atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA) in adults and children	Orphan drugs
10	Imported	Alymsys Injection (bevacizumab)	Bevacizumab	Alvogen Korea	2022-01-19	Metastatic colorectal cancer, metastatic breast cancer, non-small cell lung cancer, etc.	Biosimilar
11	Imported	AMELIVU	Ranibizumab	Samsung Bioepis	2022-05-13	Treatment of neovascular (wet) age-related macular degeneration, treatment of visual impairment due to diabetic macular edema, etc.	Biosimilar
12	Manufactured	Yuflyma Pen Inj. 80 mg/0.8 mL	Adalimumab	Celltrion	2022-06-15	Rheumatoid arthritis, Crohn's disease, psoriasis, ulcerative colitis, etc.	Biosimilar
13	Manufactured	Yuflyma Pre-filled Syringe Inj. 80 mg/0.8 mL					Biosimilar
14	Manufactured	Vegzelma	Bevacizumab	Celltrion	2022-09-28	Metastatic colorectal cancer, metastatic breast cancer, non-small cell lung cancer, etc.	Biosimilar
15	Manufactured	Chong Kun Dang Ranibizumab inj.	Ranibizumab	Chong Kun Dang Pharm.	2022-10-20	Treatment of neovascular (wet) age-related macular degeneration, treatment of visual impairment due to diabetic macular edema, etc.	Biosimilar
16	Manufactured	Celltrion Yuflyma Pen Inj. 40 mg/0.4 mL	Adalimumab	Celltrion	2022-11-10	Rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis, etc.	Biosimilar
17	Imported	Kynteles Prefilled Syringe Inj.	Vedolizumab	Takeda Pharmaceuticals Korea Co., Ltd.	2022-02-17	Ulcerative colitis, Crohn's disease	Drugs requiring data submission
18	Imported	Kynteles Prefilled Pen Inj.					Drugs requiring data submission

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/Effectiveness (partially summarized)	Remarks
19	Manufactured	Celltrion Ramxima Prefilled Syringe Inj. 120 mg	Infliximab	Celltrion	2022-03-07	Adult Crohn's disease, ankylsoing spondylitis, etc.	Drugs requiring data submission
20	Manufactured	Eutropin S Pen Inj.	Somatropin	LG Chem	2022-04-13	Growth failure due to pituitary growth hormone secretion disorder, etc.	Drugs requiring data submission
21	Imported	Skyrizi Prefilled Pen Inj. 150 mg/mL	Risankizumab	AbbVie Korea Ltd.	2022-04-22	Plaque psoriasis, psoriatic arthritis	Drugs requiring data submission
22	Imported	Skyrizi Prefilled Syringe Inj. 150 mg/mL					Drugs requiring data submission
23	Imported	Rybelsus Tab.	Semaglutide	Novo Nordisk Pharma Korea, Ltd.	2022-05-02	Adjuvant drug for diet and exercise therapy to improve blood sugar control in adults with insufficient control of type 2 diabetes.	Drugs requiring data submission
24	Imported	Dupixent Prefilled Pen Inj. 200 mg	Dupilumab	Sanofi-aventis Korea Co., Ltd.	2022-05-19	Atopic dermatitis, asthma	Drugs requiring data submission
25	Imported	Dupixent Prefilled Pen Inj. 300 mg				Chronic rhinosinusitis with atopic dermatitis, asthma, and polyps	Drugs requiring data submission
26	Imported	Jivi Inj.	Damoctocog alfa pegol (blood coagulation factor VIII)	Bayer Korea Ltd.	2022-07-05	Prevention of bleeding in adults and adolescents (aged 12 years or older) with hemophilia A (congenital deficiency of coagulation factor VIII)	Drugs requiring data submission
27	Imported	Gonal-F Pen 150IU Inj.	Follitropin-α	Merck	2022-09-29	Controlled ovarian hyperstimulation to mature follicles during assisted reproductive programs, etc.	Drugs requiring data submission
28	Manufactured	Celltrion Ramsima Pen Inj. 120 mg	Infliximab	Celltrion	2022-10-28	Adult Crohn's disease, ankylsoing spondylitis, etc.	Drugs requiring data submission
29	Imported	Cosentyx UnoReady Pen 300 mg/2 mL	Secukinumab	Novartis Pharma Korea ltd.	2022-11-01	Plaque psoriasis, psoriatic arthritis, axial spondyloarthritis	Drugs requiring data submission
30	Imported	Trulicity 3.0 mg/0.5 mL Single-Dose Pen	Dulaglutide	Lily Korea	2022-11-02	Adjuvant drug for diet and exercise therapy to improve blood sugar control in adults with type 2 diabetes.	Drugs requiring data submission
31	Imported	Trulicity 4.5 mg/0.5 mL Single-Dose Pen					Drugs requiring data submission

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

Table 44. List of Approved Biosimilar Products (2012-2022)

No.	Product Name	Company	Reference Drug (ingredient)	Efficacy/ Effectiveness (partially summarized)	Approval Date	Manufactured/ Imported
1	Remsima Inj. 100 mg	Celltrion	Remicade (Infliximab)	Rheumatoid arthritis, ulcerative colitis, etc.	2012-07-20	Manufactured
2	Herzuma Inj. 150 mg	Celltrion	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2014-01-15	Manufactured
3	Herzuma Inj. 440 mg					Manufactured
4	Scitropin A Cartridge Inj. 5 mg	SciGen Korea Co.,Ltd	Genotropin (Somatropin)	Growth failure in children, etc.	2014-01-.28	Imported
5	Scitropin A Cartridge Inj. 10 mg					Imported
6	Davictrel Inj. 25 mg	Hanwha Chemical	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2014-11-11 (Withdrawn on 2015-09-30)	Manufactured
7	Brenzys 50 mg Prefilled Syringe → (name changed to) Etoloce 50 mg solution for injection in pre-filled syringe	Samsung Bioepis	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2015-09-07	Imported (developed in Korea)
8	Basaglar Cartridge 100 Units/mL	Lily Korea	Lantus (Insulin glargine)	Diabetes	2015.-11-25 (Withdrawn on 2019-09-26)	Imported
9	Basaglar Kwikpen 100 Units/mL				2015-11-25	Imported
10	Renflexis Inj. 100 mg → (name changed to) Remaloce Inj. 100 mg	Samsung Bioepis	Remicade (Infliximab)	Rheumatoid arthritis, ulcerative colitis, etc.	2015-12-04	Imported (developed in Korea)
11	Truxima Inj.	Celltrion	MabThera Inj. (Rituximab)	Rheumatoid arthritis, lymphoma, etc.	2015-07-16 2016-11-16 (Switched for demestic use)	Manufactured
12	Hadlima Prefilled Syringe Inj. 40 mg → (name changed to) Adaloce Prefilled Syringe Injection 40 mg	Samsung Bioepis	Humira Inj. 40 mg (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis, etc.	2017-09-20	Imported (developed in Korea)
13	Samfenet Inj. 150 mg	Samsung Bioepis	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2017-11-08	Imported (developed in Korea)
14	Glarzia Prefilled Pen	GC Biopharma Corp.	Lantus (Insulin glargine)	Diabetes	2018-03-07	Imported
15	Eucept Prefilled Syringe Inj.	LG Chem	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2018-03-16	Manufactured
16	Eucept Auto Injector Inj.					Manufactured

No.	Product Name	Company	Reference Drug (ingredient)	Efficacy/ Effectiveness (partially summarized)	Approval Date	Manufactured/ Imported
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	Enbrel (Etanercept)	Rheumatoid arthritis, psoriasis, etc.	2019-08-19	Imported (developed in Korea)
23	Terrosa Cartridge Inj.	Daewon Pharm.	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	Humira Inj. 40 mg (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis etc.	2020-07-03	Imported (developed in Korea)
27	Ogivri Injection 150 mg	Alvogen Korea	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2020-08-26	Imported
28	Samfenet Injection 440 mg	Samsung Bioepis	Herceptin Inj. (Trastuzumab)	Breast cancer, gastric cancer	2020-10-14	Imported (developed in Korea)
29	Bemfola Prefilled Pen	YooYoung Pharmaceutical Co., Ltd	Gonal-F Pen Inj. (Follitropin-α)	Ovarian hyperstimulation, anovulation	2020-10-29	Imported
30	Onbevzi Inj.	Samsung Bioepis	Avastin (Bevacizumab)	Metastatic colorectal cancer, etc.	2021-03-11	Imported (developed in Korea)
31	Zyrabev	Pfizer Pharmaceuticals Korea Limited	Avastin (Bevacizumab)	Metastatic colorectal cancer, etc.	2021-05-17	Imported
32	Scitropin A Cartridge Inj. 15 mg	SciGen Korea Co., Ltd	Genotropin (Somatropin)	Growth failure in children, etc.	2021-07-09	Imported
33	Yuflyma PFS 40 mg/0.4 mL	Celltrion	Humira 40mg/0.4mL (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis etc.	2021-10-15	Imported (developed in Korea)
34	Yuflyma Pen Inj. 40 mg/0.4 mL					Imported (developed in Korea)
35	Bonsity pen Inj(Teriparatide)	Pharmbio Korea	Forsteo (Teriparatide)	Osteoporosis	2021-11-16	Imported
36	Alymsys Injection (bevacizumab)	Alvogen Korea	Avastin (Bevacizumab)	Metastatic colorectal cancer, etc.	2022-01-19	Imported
37	AMELIVU	Samsung Bioepis	Lucentis Inj. (Ranibizumab)	Age-related macular degeneration, etc.	2022-05-13	Imported (developed in Korea)
38	Yuflyma Pen Inj. 80 mg/0.8 mL	Celltrion	Humira 80mg/0.8mL (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis etc.	2022-06-15	Manufactured
39	Yuflyma PFS 80 mg/0.8					Manufactured

No.	Product Name	Company	Reference Drug (ingredient)	Efficacy/ Effectiveness (partially summarized)	Approval Date	Manufactured/ Imported
	mL					
40	Vegzelma	Celltrion	Avastin (Bevacizumab)	Metastatic colorectal cancer, etc.	2022-09-28	Manufactured
41	Chong Kun Dang Ranibizumab inj	Chong Kun Dang Pharm.	Lucentis Inj. (Ranibizumab)	Age-related macular degeneration, etc.	2022-10-20	Manufactured
42	Celltrion Yuflyma Pen Inj. 40 mg/0.4 mL	Celltrion	Humira 40mg/0.4mL (Adalimumab)	Rheumatoid arthritis, psoriatic arthritis etc.	2022-11-10	Manufactured

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

3.3. Approval Status of Advanced Biopharmaceutical Products

1) Approval Status of Cell Therapy Products

With the enactment of the Act on Safety and Support for Advanced Regenerative Medicine and Advanced Biopharmaceutical Products (hereafter referred to as the Advanced Regenerative Bio Act), the approval system, previously focused on synthetic drugs and traditional biologics, has been reorganized to suit the characteristics of advanced biopharmaceutical products.

In accordance with the Advanced Regenerative Bio Act, there were no cell therapy products approved in 2022, after re-approval of 15 items in 2021.

Table 45. List of Approved Cell Therapy Products (2001-2022)

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Initial Approval Date	Re-Approval Date	Efficacy/ Effectiveness (partially summarized)	Remarks
1	Manufactured	Chondron	RMS autologous cartilage-derived chondrocyte	Cellontech Co., Ltd.	2001-01-30	2021-08-26	Treatment of focal cartilage defect in knee joint (defect size: not more than 15cm^2 in single lesion, not more than 20 cm^2 in multiple lesion)	
2	Manufactured	Holoderm	Autologous keratinocyte	Tego Science, Inc	2002-12-10	2021-08-27	Creation of functional epidermis by transplanting to: 1. The burn where second degree burn takes not less than 30% of the body surface area 2. The burn where third degree burn takes not less than 10% of the body surface	

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Initial Approval Date	Re-Approval Date	Efficacy/ Effectiveness (partially summarized)	Remarks
3	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 does not have findings of infection	
4	Manufactured	Keraheal	Basol autologous keratinocyte	Biosolution Co., Ltd.	2006-05-03	2021-08-25	Creation of functional epidermis by transplanting to: 1. The burn where second degree burn takes not less than 30% of the body surface area 2. The burn where third degree burn takes not less than 10% of the body surface	
5	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)	
6	Manufactured	RMS Ossron	RMS autologous bone marrow-derived osteocyte	Cellontech Co., Ltd.	2009-08-26	2021-08-06	Promoting local bone formation	
7	Manufactured	Queencell	Minimally manipulated autologous adipose tissue-derived fat cell	Anterogen Co., Ltd.	2010-03-26	2021-06-09	Improvement of subcutaneous fat defect	
8	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	

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Initial Approval Date	Re-Approval Date	Efficacy/ Effectiveness (partially summarized)	Remarks
9	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	
10	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)	
11	Manufactured	Cupistem Inj.	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
12	Manufactured	Neuronata ® inj.	Autologous bone marrow-derived mesenchymal stem cell	Corestem Inc.	2014-07-30	2021-08-27	Alleviate the disease progression rate of amyotrophic lateral sclerosis in combination with riluzole	Orphan drug
13	Manufactured	Keraheal-Allo	Basol allogeneic keratinocyte	Biosolution Co., Ltd.	2015-10-16	2021-08-25	Promoting re-epithelization of deep second degree burn	
14	Manufactured	Rosmir	Tego autologous fibroblast	Tego Science, Inc	2017-12-27	2021-08-24	Improvement of moderate-to-severe nasojugal groove	
15	Manufactured	Cartilife	Basol autologous cartilage-derived chondrocyte	Biosolution Co., Ltd.	2019-04-24	2021-07-22	Treatment of knee cartilage defect (ICRS grade III or IV, defect area 2 to 10 cm^2)	

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

2) Approval Status of Gene Therapy Agents

Since 3 items, including “Kimriah Inj.,” were approved in 2021, there were no newly approved gene therapy agents in 2022.

Table 46. List of Approved Gene Therapy Agents (2021-2022)

No.	Manufactured/ Imported	Product Name	Ingredient	Company	Approval Date	Efficacy/Effectiveness	Remarks
1	Imported	Kymriah Inj.	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	New orphan drug
2	Imported	Zolgensma Inj.	Onasemnogene abeparvovec	Novartis Korea	2021-05-28	Patient with Spinal Muscular Atrophy (SMA) with a biallelic mutation in the Survival Motor Neuron 1 (SMN1) gene falling under any of the following: - Clinically diagnosed with Type 1 - 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	New orphan drug

4

Approval Status of Herbal(Oriental) Medicines

4. Approval Status of Herbal(Oriental) Medicines

In 2022, 8 items of herbal(oriental) medicines were approved (refer to Table 47).

Analyzing by review type, 1 item was a drug requiring data submission with a new composition and specification. In addition, there were 1 item exempted from safety/efficacy based on its existence in a foreign compendium, 2 items based on the prescriptions in Korean traditional herbal medicine books, 3 miscellaneous items, and 1 item of drug substance.

Table 47. Herbal(Oriental) Medicines Approved in 2022 by Review Type

(Unit: Number of items)

Type	Review Type			Number of Approved Items	
1	New Drugs (0)	New Drugs		0	
2		New Orphan Drugs	Orphan Drugs (0)	0	
3	Orphan Drugs			0	
4	Drugs requiring data submission			1	
4-1	Incrementally modified drugs			0	
4-2	Drugs requiring data submission	New composition and specification		1	1
4-3		Change in strength		0	
4-4		New drug efficacy/effectiveness, mode of administration/dosage		0	
4-5					
4-6		New route of administration		0	
4-7		New dosage form		0	
4-8		Literature evidence other than Korean traditional herbal medicine books		0	
5	verification of equivalence			0	
6	Others	Exempt from safety and efficacy data submission		7	1
		Prescriptions in Korean traditional herbal medicine books			2
		Others			3
		Drug substances			1
		Medicinal Herbs			0

When categorized according to the drug classification criteria, all approved items were manufactured, and includes 1 ETC drug, 6 OTC drugs, and 1 drug substances (refer to Table 48).

Table 48. Herbal(Oriental) Medicines Approved in 2022

(Unit: Number of items)

Type	Category	Total	Item Approval			
			ETC	OTC	Drug Substance	Medicinal Herbs
Total		8	1	6	1	0
Herbal medicinal products, etc.	Manufactured	8	1	6	1	0
	Imported	0	0	0	0	0

4.1. Approval Status of New Herbal(Oriental) Medicinal Products

There have been no new herbal(oriental) medicinal products since 2014, but one domestically developed new herbal(oriental) medicinal product was approved in 2021, and no new drug was approved in 2022 (see Table 49).

Table 49. Herbal(Oriental) Medicinal Products Approved as New Drugs Annually (2010-2022)

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

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

1 item of herbal(oriental) medicinal products with new composition and specification was approved as a drug requiring data submission in 2022 (refer to Table 50).

Table 50. Drugs Requiring Data Submission Approved in 2022

Review Type of Drugs Requiring for Data Submission	Number of Approved Items
New composition and specification	1
Total	1

4.2.1. Drugs with New Composition and Specification (1 item)

1 item (1 manufactured item) of a new composition and specification drug was developed by changing the extraction method (refer to Table 51).

"GTEC Tab. 75mg(Cinnamon Bark Dried Extract(16~26→1))" (Chong Kun Dang Pharm., 2022.07.08.) was developed for the purpose of improving gastric mucosal lesions in acute and chronic gastritis by changing the method of extracting cinnamon bark by water, into that of using purified water for extraction following pre-treatment with ethyl acetate.

Table 51. Drugs Requiring Data Submission with New Composition and Specification Approved in 2022

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Detailed Classification	Active Ingredient
1	Manufactured	GTEC Tab. 75mg(Cinnamon Bark Dried Extract(16~26→1))	Chong Kun Dang Pharm.	2022-07-18	Peptic ulcer drugs	Cinnamon Bark Dried Ext. (16-26→1)

4.3 Approval Status of Other Herbal(Oriental) Medicinal Products

Among the miscellaneous herbal(oriental) medicinal products approved in 2022, there were 6 ETC drugs domestically manufactured with 6 ingredients.

“Hanpoong youngseanjetongeum soft Extract” (Hanpoong PHARM. Co., Ltd., 2022.02.14.) is formulated with a new dosage form (extract), but has the same administration route as what is listed in the Korean traditional herbal medicine book (Donguibogam) and it is used for rheumatoid arthritis and neuralgia.

“Kyungbang Ijintang Soft Extract (Mix Extract Powder)” (KBPharm Inc., 2022.02.16.) is a mix soft extract approved for Korean national health insurance based on “Ijintang Soft Extract” listed in the Korean herbal pharmacopeia.

“Kyungbang Saengmaeksan Soft Extract (Mix Extract Powder)” (KBPharm Inc., 2022.03.08.) is formulated with a new dosage form (extract), but has the same administration route as what is listed in the Korean traditional herbal medicine book (Donguibogam, Korean herbal pharmacopeia), and was approved for Korean national health insurance.

“Stimorin S Cream” (Sinil Pharm, 2022.03.25.) has a different strength from that of the previously approved product, but is exempted from safety and efficacy data submission as it already exists in a foreign compendium pursuant to the Regulation on Approval and Notification of Herbal(oriental) Medicinal Products, etc., and is used for the purpose of treating superficial skin erosion and pressure ulcers.

In the case of **“Haruryeok solution”** (IKSU Pharmaceutical, 2022.07.07.) and **“Misojin solution”** (IKSU Pharmaceutical, 2022.07.15.), there had been previously approved items but at the time of approval, they were new items without previously approved items. The former was approved as an item used for loss of stamina, fatigue and boredom, loss of appetite (anorexia), night sweats (symptoms in which someone sweats while sleeping at night, but does not feel it and stop sweating when someone wake up), cold hands and feet, anemia, and the latter as an item used for nourishment, fatigue recovery, and assistance and improvement of weak constitutions.

4.4 Approval Status of Drug Substances and Medicinal Herbs

1 item was approved as a drug substance for herbal(oriental) medicines, and there were no items approved as medicinal herbs (refer to Table 52).

Table 52. Herbal(oriental) Medicines Approved in 2022 (Drug Substances and Medicinal Herbs)

No.	Manufactured/ Imported	Product Name	Company	Approval Date	Remarks
1	Manufactured	BncKoreaBaenongsangeuptangDryExtract (7→1)(Drug Substance)	BNC Korea	2021-07-07	Drug substance

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

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 2023)

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 devices subject to approval and Class III/IV devices) ·Classification and approval of products in which drugs, quasi-drugs and medical devices are physically/chemically 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)
	Clinical Trials Policy Division	·Approval of clinical trial plans

Category	Department		Detailed Petition Service
			·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	Pharmaceutical	·Review of registration data of drug substances

Category	Department		Detailed Petition Service
	Evaluation Department	Standardization Division	(excluding substances of new drugs) ·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 Biopharmaceutical Products TF)		GMP evaluation for advanced biopharmaceutical 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 biopharmaceutical 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

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Editor in Chief	Oh-Sang Kwon		
Editors	Eunjoo Kim,	Kiseok Kim,	Younsu Kim,
	Junghwa Lee,	Jihye Lee,	Hyunju Moon,
	Sangmi Lim,	Sukyung Ahn,	Sanghwa Ryu,
	Sunyeong Yang,	Kyeorye Lee,	Jieun Lee,
	Dajung Kang,	Jiyeong Lee,	Wonhee Kim,
	Sukhyeon Um,	Suji Hong,	Daeun Lee,
	Hyunjoon Hwang,	Geunah Lee,	Jongsook Park,
	Namyun Kim,	Hyang Park,	Heejung Jung,
	Seonyoung Park,	Songwon Jeon,	Minjeong Park,
	Eeray Kim (Director for Novel Products Approval)		Namsu Kim,
	Jusun Nam,	Miae Kim,	Moah Jung
Organization	Director for Approval Management, 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