

Appendix

Table 1. Characteristics, Generic Entry, and Market Exclusivity of New Small-molecule Drugs Approved in China Between 2003 and 2020.

No.	Generic name	Approval date of new drugs in China	Number of active ingredients	Therapeutic areas ¹	Dosage form	Domestic or Imported	Having generic entry	Approval date of first generics in China	Length of Market exclusivity (years)
1	Gadobenate Dimeglumine	2003/2/13	Single	V	Solution	Imported	Yes	2020/1/15	16.9
2	Iron Sucrose	2003/3/26	Single	B	Solution	Imported	Yes	2004/10/27	1.6
3	Lopinavir and Ritonavir	2003/3/31	Compound	J	Other	Imported	No	/	/
4	Desloratadine	2003/4/1	Single	R	Oral common-release	Imported	Yes	2004/7/19	1.3
5	Chloroquinoline	2003/4/23	Single	L	Oral common-release	Domestic	No	/	/
6	Nateglinide	2003/5/9	Single	A	Oral common-release	Imported	Yes	2004/3/26	0.9
7	Tandospirone	2003/5/21	Single	N	Oral common-release	Imported	Yes	2020/3/30	16.9
8	Irinotecan	2003/5/23	Single	L	Solution	Imported	Yes	2009/1/4	5.6
9	Sulphur Hexafluoride	2003/5/23	Single	V	Solution	Imported	No	/	/
10	Brimonidine	2003/6/2	Single	S	Other	Imported	Yes	2004/9/17	1.3
11	Irbesartan and Hydrochlorothiazide	2003/6/9	Compound	C	Oral common-release	Imported	Yes	2005/5/27	2.0
12	Tirofiban	2003/6/13	Single	B	Solution	Imported	Yes	2004/6/21	1.0
13	Lamivudine	2003/6/16	Single	J	Oral common-release	Imported	Yes	2009/5/6	5.9
14	Rociverine	2003/6/20	Single	A	Oral common-release	Imported	No	/	/
15	Raloxifene	2003/7/3	Single	G	Oral common-release	Imported	Yes	2005/5/27	1.9
16	Beraprost Sodium	2003/8/15	Single	B	Oral common-release	Imported	Yes	2008/6/27	4.9
17	Deferiprone	2003/9/23	Single	V	Other	Imported	No	/	/
18	Alendronate sodium	2003/9/23	Single	M	Oral common-release	Imported	Yes	2005/9/9	2.0
19	Alfuzosin	2003/11/13	Single	G	Other	Imported	Yes	2006/5/12	2.5
20	Busulfan	2003/12/12	Single	L	Oral common-release	Imported	Yes	2015/12/30	12.0
21	Perindopril	2003/12/12	Single	C	Oral common-release	Imported	Yes	2009/4/29	5.4
22	Midazolam	2004/1/21	Single	N	Oral common-release	Imported	Yes	2006/7/27	2.5
23	Oxycodone	2004/1/21	Single	N	Other	Imported	Yes	2009/5/21	5.3
24	Valsartan	2004/1/21	Single	C	Oral common-release	Imported	Yes	2005/2/23	1.1
25	Betahistine	2004/1/21	Single	N	Oral common-release	Imported	Yes	2004/7/5	0.5
26	Quercus Salicina Extract	2004/2/13	Single	G	Oral common-release	Imported	No	/	/
27	Bupropion	2004/2/13	Single	N	Other	Imported	Yes	2004/3/5	0.1
28	Hydroxyethyl Starch 130/0.4	2004/4/8	Single	B	Solution	Imported	Yes	2006/6/22	2.2
29	Articaine and Epinephrine	2004/4/30	Single	N	Solution	Imported	No	/	/
30	Tribendimidine	2004/4/30	Single	P	Oral common-release	Domestic	No	/	/
31	Entacapone	2004/5/8	Single	N	Oral common-release	Imported	Yes	2021/3/23	16.9
32	Citrus Bioflavonoids	2004/6/4	Single	C	Oral common-release	Imported	No	/	/
33	Boanmycin	2004/6/24	Single	L	Solution	Domestic	No	/	/

34	Uroacitides	2004/7/23	Single	L	Solution	Domestic	No	/	/
35	Vardenafil	2004/8/5	Single	G	Oral common-release	Imported	Yes	2020/7/27	16.0
36	Carbetocin	2004/10/20	Single	H	Solution	Imported	Yes	2016/1/5	11.2
37	Indometacin	2004/10/21	Single	C	Other	Imported	Yes	2005/8/26	0.8
38	Valsartan and Hydrochlorothiazide	2004/10/21	Compound	C	Oral common-release	Imported	Yes	2004/12/15	0.2
39	Voriconazole	2004/10/21	Single	J	Oral common-release	Imported	Yes	2005/6/24	0.7
40	formoterol and budesonide	2004/11/17	Compound	R	Other	Imported	No	/	/
41	Gefitinib	2004/12/6	Single	L	Oral common-release	Imported	Yes	2016/12/30	12.1
42	Travoprost	2004/12/7	Single	S	Other	Imported	Yes	2017/8/29	12.7
43	Verteporfin Powder	2004/12/7	Single	S	Solution	Imported	No	/	/
44	Artemisinin and Pipleraquine	2004/12/7	Compound	P	Oral common-release	Domestic	No	/	/
45	Tadalafil	2004/12/28	Single	G	Oral common-release	Imported	Yes	2019/2/14	14.1
46	Diacerein	2005/1/4	Single	M	Oral common-release	Imported	No	/	/
47	Bortezomib	2005/2/21	Single	L	Solution	Imported	Yes	2017/11/30	12.8
48	Cetorelix	2005/2/21	Single	H	Solution	Imported	Yes	2018/12/5	13.8
49	Iomeprol	2005/2/25	Single	V	Solution	Imported	No	/	/
50	Estradiol and Dydrogesterone	2005/3/11	Compound	G	Oral common-release	Imported	No	/	/
51	Adefovir Dipivoxil	2005/3/23	Single	J	Oral common-release	Imported	Yes	2005/4/22	0.1
52	Tramadol and Paracetamol	2005/4/1	Compound	N	Oral common-release	Imported	Yes	2008/4/2	3.0
53	Bimatoprost	2005/4/20	Single	S	Other	Imported	Yes	2021/2/5	15.8
54	Tiotropium Bromide	2005/5/10	Single	R	Other	Imported	Yes	2006/5/18	1.0
55	Iloprost	2005/5/25	Single	B	Other	Imported	No	/	/
56	Mivacurium Chloride	2005/8/11	Single	M	Solution	Imported	Yes	2021/3/30	15.6
57	Acehytisine	2005/8/22	Single	C	Solution	Domestic	No	/	/
58	Sophoridine	2005/8/22	Single	L	Solution	Domestic	No	/	/
59	Escitalopram	2005/8/31	Single	N	Oral common-release	Imported	Yes	2008/10/8	3.1
60	Perindopril and Indapamide	2005/9/7	Compound	C	Oral common-release	Imported	Yes	2021/7/20	15.9
61	Ertapenem Sodium	2005/9/12	Single	J	Solution	Imported	Yes	2013/11/4	8.1
62	Naftifine and Ketoconazole	2005/9/26	Compound	D	Other	Domestic	No	/	/
63	Pimecrolimus	2005/9/29	Single	D	Other	Imported	No	/	/
64	Urinary Kallidinogenase	2005/10/19	Single	N	Solution	Domestic	No	/	/
65	Calf Pulmonary Surfactant	2005/10/28	Single	R	Solution	Domestic	No	/	/
66	Entecavir	2005/11/15	Single	J	Oral common-release	Imported	Yes	2010/2/11	4.2
67	Sertaconazole	2005/11/15	Single	D	Other	Imported	Yes	2015/4/8	9.4
68	Valganciclovir	2005/12/13	Single	J	Oral common-release	Imported	No	/	/
69	Pramipexole	2005/12/30	Single	N	Oral common-release	Imported	Yes	2018/8/27	12.7
70	Bosentan	2006/3/23	Single	C	Oral common-release	Imported	No	/	/
71	Erlotinib	2006/4/6	Single	L	Oral common-release	Imported	Yes	2019/9/26	13.5
72	Atosiban	2006/4/6	Single	G	Solution	Imported	Yes	2013/4/2	7.0
73	Ezetimibe	2006/4/6	Single	C	Oral common-release	Imported	Yes	2020/9/16	14.4

74	Oltmesartan Medoxomil	2006/4/6	Single	C	Oral common-release	Imported	Yes	2007/1/16	0.8
75	Micafungin	2006/5/12	Single	J	Solution	Imported	Yes	2018/4/20	11.9
76	Atomoxetine	2006/5/12	Single	N	Oral common-release	Imported	Yes	2009/1/16	2.7
77	Menotropins	2006/5/30	Single	G	Solution	Imported	No	/	/
78	Menotrophin	2006/5/30	Single	G	Solution	Imported	No	/	/
79	Duloxetine	2006/7/28	Single	N	Oral common-release	Imported	Yes	2006/9/15	0.1
80	Sorafenib	2006/9/12	Single	L	Oral common-release	Imported	Yes	2020/8/12	13.9
81	Memantine	2006/9/12	Single	N	Oral common-release	Imported	Yes	2013/7/19	6.9
82	Linezolid	2006/9/12	Single	J	Oral common-release	Imported	Yes	2015/5/13	8.7
83	Policosanol	2006/9/12	Single	C	Oral common-release	Imported	No	/	/
84	Levetiracetam	2006/11/22	Single	N	Oral common-release	Imported	Yes	2014/6/17	7.6
85	Polyethylene Glycol	2006/12/20	Single	B	Other	Imported	No	/	/
86	Nicorandil	2006/12/20	Single	C	Oral common-release	Imported	Yes	2012/9/11	5.7
87	Mepivacaine	2006/12/20	Single	N	Solution	Imported	Yes	2011/6/2	4.4
88	Rosuvastatin	2006/12/27	Single	C	Oral common-release	Imported	Yes	2008/5/9	1.4
89	Loteprednol	2007/1/10	Single	S	Other	Imported	No	/	/
90	Telbivudine	2007/2/14	Single	J	Oral common-release	Imported	No	/	/
91	Capecitabine	2007/2/14	Single	L	Oral common-release	Imported	Yes	2013/12/20	6.8
92	Etoricoxib	2007/5/21	Single	M	Oral common-release	Imported	Yes	2019/9/26	12.4
93	Cyclopentolate	2007/7/23	Single	S	Other	Imported	Yes	2007/12/21	0.4
94	Sunitinib	2007/10/30	Single	L	Oral common-release	Imported	Yes	2020/1/6	12.2
95	Ilaprazole	2007/12/11	Single	A	Oral common-release	Domestic	No	/	/
96	Eprosartan	2007/12/28	Single	C	Oral common-release	Imported	No	/	/
97	Fondaparinux Sodium	2008/3/24	Single	B	Solution	Imported	Yes	2018/5/30	10.2
98	Parecoxib Sodium	2008/3/24	Single	M	Solution	Imported	Yes	2017/11/30	9.7
99	Amlodipine Besylate and Atorvastatin Calcium	2008/4/3	Compound	C	Oral common-release	Imported	Yes	2021/6/16	13.2
100	Alendronate Sodium and Vitamin D3	2008/5/22	Compound	M	Oral common-release	Imported	Yes	2011/6/30	3.1
101	Tenofovir Disoproxil	2008/6/18	Single	J	Oral common-release	Imported	Yes	2016/11/30	8.5
102	Drospirenone and EthinylEstradiol	2008/6/30	Compound	G	Oral common-release	Imported	No	/	/
103	Latanoprost and Timolol	2008/6/30	Compound	S	Other	Imported	Yes	2017/11/30	9.4
104	Varenicline	2008/7/31	Single	N	Oral common-release	Imported	Yes	2021/4/20	12.7
105	Calcipotriol Betamethasone	2008/9/1	Compound	D	Other	Imported	No	/	/
106	Decitabine	2008/9/28	Single	L	Solution	Imported	Yes	2012/10/18	4.1
107	Paliperidone	2008/9/28	Single	N	Other	Imported	Yes	2020/6/22	11.7
108	Pitavastatin Calcium	2008/9/28	Single	C	Oral common-release	Imported	Yes	2008/11/18	0.1
109	Mycophenolate	2008/12/19	Single	L	Oral common-release	Imported	Yes	2021/3/30	12.3
110	Etonogestrel	2009/1/4	Single	G	Other	Imported	No	/	/
111	Compound Methyl Salicylate and	2009/1/4	Compound	V	Other	Imported	No	/	/

Menthol									
112	Tegafur, Gimeracil and Oteracil Potassium	2009/1/9	Single	L	Oral common-release	Imported	Yes	2010/11/2	1.8
113	Cefotaxime and Sulbactam	2009/1/16	Compound	J	Solution	Domestic	No	/	/
114	Ceftriaxone and Tazobactam	2009/3/10	Compound	J	Solution	Domestic	Yes	2019/12/26	10.8
115	Rivaroxaban	2009/3/31	Single	B	Oral common-release	Imported	Yes	2019/8/8	10.4
116	Ezetimibe and Simvastatin	2009/4/15	Compound	C	Oral common-release	Imported	No	/	/
117	Antofloxacin	2009/4/15	Single	J	Oral common-release	Domestic	No	/	/
118	Exenatide	2009/5/8	Single	A	Solution	Imported	No	/	/
119	Solifenacin	2009/5/22	Single	G	Oral common-release	Imported	Yes	2018/8/17	9.2
120	Ibuprofen, Pseudoephedrine and Chlorphenamine	2009/5/22	Single	N	Other	Imported	Yes	2014/1/6	4.6
121	Teprenone	2009/5/31	Single	A	Oral common-release	Imported	No	/	/
122	Zanamivir	2009/7/1	Single	J	Other	Imported	Yes	2010/2/11	0.6
123	Nilotinib	2009/7/14	Single	L	Oral common-release	Imported	No	/	/
124	Levornidazole	2009/8/13	Single	J	Solution	Domestic	Yes	2017/12/28	8.4
125	Daptomycin	2009/9/2	Single	J	Solution	Imported	Yes	2015/11/19	6.2
126	Estradiol and Drospirenone	2009/9/29	Compound	G	Oral common-release	Imported	No	/	/
127	Sitagliptin	2009/9/29	Single	A	Oral common-release	Imported	Yes	2020/2/27	10.4
128	Valsartan and Amlodipine	2009/9/29	Compound	C	Oral common-release	Imported	Yes	2020/2/6	10.4
129	Bromfenac Sodium	2009/9/29	Single	S	Other	Imported	Yes	2015/4/22	5.6
130	Ecabet	2010/3/15	Single	A	Other	Imported	Yes	2018/4/12	8.1
131	Olmesartan Medoxomil and Hydrochlorothiazide	2010/3/15	Compound	C	Oral common-release	Imported	Yes	2020/8/19	10.4
132	Aliskiren	2010/3/26	Single	C	Oral common-release	Imported	No	/	/
133	Pregabalin	2010/5/7	Single	N	Oral common-release	Imported	Yes	2013/7/3	3.2
134	Bepotastine	2010/5/7	Single	R	Oral common-release	Imported	Yes	2019/12/23	9.6
135	Fulvestrant	2010/6/4	Single	L	Solution	Imported	Yes	2020/8/19	10.2
136	Deferasirox	2010/6/12	Single	V	Oral common-release	Imported	Yes	2021/6/18	11.0
137	Menatetrenone	2010/6/29	Single	M	Oral common-release	Imported	No	/	/
138	Sapropterin	2010/9/25	Single	A	Oral common-release	Imported	No	/	/
139	Gadoxetic Acid Disodium	2010/9/25	Single	V	Solution	Imported	Yes	2019/6/12	8.7
140	Ambrisentan	2010/10/19	Single	C	Oral common-release	Imported	Yes	2018/8/7	7.8
141	Tigecycline	2010/11/9	Single	J	Solution	Imported	Yes	2012/12/19	2.1
142	Dapoxetine	2010/12/10	Single	G	Oral common-release	Imported	Yes	2020/4/16	9.3
143	Ceftriaxone and Sulbactam	2010/12/28	Compound	J	Solution	Domestic	No	/	/
144	Carteolol	2011/1/25	Single	S	Other	Imported	No	/	/
145	Teriparatide	2011/3/4	Single	H	Solution	Imported	Yes	2017/3/22	6.1
146	Liraglutide	2011/3/4	Single	A	Solution	Imported	No	/	/
147	Agomelatine	2011/4/2	Single	N	Oral common-release	Imported	Yes	2014/12/18	3.7
148	Dutasteride	2011/4/11	Single	G	Oral common-release	Imported	Yes	2020/1/16	8.8

149	Saxagliptin	2011/5/5	Single	A	Oral common-release	Imported	Yes	2019/1/17	7.7
150	Clobetasone	2011/5/5	Single	D	Other	Imported	Yes	2017/12/28	6.7
151	Imrecoxib	2011/5/20	Single	M	Oral common-release	Domestic	No	/	/
152	Icotinib	2011/6/7	Single	L	Oral common-release	Domestic	No	/	/
153	Vildagliptin	2011/8/15	Single	A	Oral common-release	Imported	Yes	2019/3/19	7.6
154	Bivalirudin	2011/8/15	Single	B	Solution	Imported	Yes	2011/8/23	0.0
155	Iguratimod	2011/8/15	Single	M	Oral common-release	Domestic	No	/	/
156	Silodosin	2011/8/25	Single	G	Oral common-release	Imported	Yes	2021/7/28	9.9
157	Dasatinib	2011/9/7	Single	L	Oral common-release	Imported	Yes	2013/9/27	2.1
158	Tolvaptan	2011/9/7	Single	C	Oral common-release	Imported	Yes	2021/3/4	9.5
159	Lanthanum Carbonate Chewable	2012/2/10	Single	V	Oral common-release	Imported	Yes	2020/2/24	8.0
160	Loteprednol Etabonate and Tobramycin	2012/2/10	Compound	S	Other	Imported	No	/	/
161	Indacaterol	2012/6/15	Single	R	Other	Imported	No	/	/
162	Paracetamol and Dexchlorpheniramine	2012/6/27	Compound	N	Other	Imported	No	/	/
163	Sitagliptin and Metformin	2012/7/23	Compound	A	Oral common-release	Imported	Yes	2020/8/21	8.1
164	Abacavir and Lamivudine	2012/7/23	Compound	J	Oral common-release	Imported	No	/	/
165	Entacapone, Levodopa and Carbidopa	2012/8/16	Compound	N	Oral common-release	Imported	No	/	/
166	Estradiol and Cyproterone	2012/8/23	Compound	G	Oral common-release	Imported	No	/	/
167	Ticagrelor	2012/11/22	Single	B	Oral common-release	Imported	Yes	2018/8/7	5.7
168	Emtricitabine and tenofovir disoproxil fumarate	2012/12/31	Compound	J	Oral common-release	Imported	Yes	2020/6/10	7.4
169	Prucalopride	2012/12/31	Single	A	Oral common-release	Imported	Yes	2018/12/17	6.0
170	Rilpivirine	2012/12/31	Single	J	Oral common-release	Imported	No	/	/
171	Bimatoprost and Timolol	2013/1/15	Compound	S	Other	Imported	No	/	/
172	Apixaban	2013/1/22	Single	B	Oral common-release	Imported	Yes	2019/1/17	6.0
173	Lenalidomide	2013/1/22	Single	L	Oral common-release	Imported	Yes	2017/11/30	4.9
174	Caffeine	2013/1/22	Single	N	Solution	Imported	Yes	2016/10/25	3.8
175	Lapatinib	2013/1/22	Single	L	Oral common-release	Imported	No	/	/
176	Crizotinib	2013/1/22	Single	L	Oral common-release	Imported	No	/	/
177	Everolimus	2013/1/22	Single	L	Oral common-release	Imported	No	/	/
178	Beclometasone Dipropionate and Formoterol	2013/2/4	Compound	R	Other	Imported	No	/	/
179	Dabigatran Etxilate	2013/2/22	Single	B	Oral common-release	Imported	Yes	2020/3/19	7.1
180	Linagliptin	2013/3/26	Single	A	Oral common-release	Imported	Yes	2020/7/16	7.3
181	Peramivir	2013/4/5	Single	J	Solution	Domestic	No	/	/
182	Sevelamer	2013/6/3	Single	V	Oral common-release	Imported	Yes	2020/7/16	7.1
183	Ganirelix	2013/6/3	Single	H	Solution	Imported	Yes	2018/2/23	4.7
184	Paricalcitol	2013/7/16	Single	H	Solution	Imported	Yes	2018/2/23	4.6

185	Aprepitant	2013/7/16	Single	A	Oral common-release	Imported	Yes	2020/7/23	7.0
186	Alogliptin	2013/7/16	Single	A	Oral common-release	Imported	Yes	2019/11/28	6.4
187	Polidocanol	2013/9/17	Single	C	Solution	Imported	No	/	/
188	Allisartan Isoproxil	2013/9/26	Single	C	Oral common-release	Domestic	No	/	/
189	Eperisone	2013/10/10	Single	M	Oral common-release	Imported	Yes	2020/2/20	6.4
190	Quetiapine	2013/10/24	Single	N	Oral common-release	Imported	Yes	2019/8/23	5.8
191	Bemiparin	2014/1/6	Single	B	Solution	Imported	No	/	/
192	Gadoteridol	2014/2/13	Single	V	Solution	Imported	No	/	/
193	Morinidazole	2014/2/24	Single	J	Solution	Domestic	No	/	/
194	Cinacalcet	2014/6/27	Single	H	Oral common-release	Imported	Yes	2020/4/16	5.8
195	Gadobutrol	2014/7/13	Single	V	Solution	Imported	No	/	/
196	Travoprost and Timolol	2014/9/22	Compound	S	Other	Imported	No	/	/
197	Apatinib	2014/10/17	Single	L	Oral common-release	Domestic	No	/	/
198	Brimonidine and Timolol	2014/12/9	Compound	S	Other	Imported	No	/	/
199	Metformin and Vildagliptin	2014/12/9	Compound	A	Oral common-release	Imported	Yes	2021/1/27	6.1
200	Chidamide	2014/12/23	Single	L	Oral common-release	Domestic	No	/	/
201	Brinzolamide and Timolol	2015/2/10	Compound	S	Other	Imported	No	/	/
202	Cinitapride	2015/2/10	Single	A	Oral common-release	Imported	No	/	/
203	Olmesartan Medoxomil and Amlodipine	2015/3/3	Compound	C	Oral common-release	Imported	Yes	2020/12/14	5.8
204	Ivabradine	2015/4/29	Single	C	Oral common-release	Imported	Yes	2021/5/19	6.1
205	Axitinib	2015/4/29	Single	L	Oral common-release	Imported	Yes	2021/5/19	6.1
206	Abiraterone	2015/5/6	Single	L	Oral common-release	Imported	Yes	2019/7/4	4.2
207	Tafluprost	2015/7/27	Single	S	Other	Imported	No	/	/
208	Dolutegravir	2015/12/30	Single	J	Oral common-release	Imported	No	/	/
209	Nemonoxacin	2016/5/27	Single	J	Oral common-release	Domestic	No	/	/
210	Cross-linked Sodium Hyaluronate	2016/7/28	Single	M	Solution	Imported	No	/	/
211	Hemoporfin	2016/9/29	Single	D	Solution	Domestic	No	/	/
212	Miglustat	2016/11/23	Single	A	Oral common-release	Imported	No	/	/
213	Bedaquiline	2016/11/23	Single	J	Oral common-release	Imported	No	/	/
214	Afatinib	2017/2/21	Single	L	Oral common-release	Imported	Yes	2020/6/10	3.3
215	Blonanserin	2017/2/21	Single	N	Oral common-release	Imported	No	/	/
216	Pazopanib	2017/2/21	Single	L	Oral common-release	Imported	No	/	/
217	Dapagliflozin	2017/3/10	Single	A	Oral common-release	Imported	No	/	/
218	Ruxolitinib	2017/3/10	Single	L	Oral common-release	Imported	No	/	/
219	Tofacitinib	2017/3/10	Single	L	Oral common-release	Imported	Yes	2019/9/30	2.6
220	Vemurafenib	2017/3/10	Single	L	Oral common-release	Imported	No	/	/
221	Osimertinib	2017/3/22	Single	L	Oral common-release	Imported	No	/	/
222	Regorafenib	2017/3/22	Single	L	Oral common-release	Imported	No	/	/
223	Linagliptin and Metformin	2017/3/22	Compound	A	Oral common-release	Imported	Yes	2020/8/21	3.4
224	Asunaprevir	2017/4/24	Single	J	Oral common-release	Imported	No	/	/

225	Azacitidine	2017/4/24	Single	L	Solution	Imported	Yes	2019/9/30	2.4
226	Sugammadex	2017/4/24	Single	V	Solution	Imported	No	/	/
227	Saxagliptin and Metformin	2017/5/18	Compound	A	Other	Imported	No	/	/
228	Daclatasvir	2017/6/2	Single	J	Oral common-release	Imported	No	/	/
229	Rasagiline	2017/6/16	Single	N	Oral common-release	Imported	Yes	2021/6/18	4.0
230	Sacubitril Valsartan	2017/7/26	Compound	C	Oral common-release	Imported	No	/	/
231	Dolutegravir, Abacavir and Lamivudine	2017/7/26	Compound	J	Oral common-release	Imported	No	/	/
232	Ibrutinib	2017/8/24	Single	L	Oral common-release	Imported	No	/	/
233	Ombitasvir, Paritaprevir and Ritonavir	2017/9/20	Single	J	Oral common-release	Imported	No	/	/
234	Dasabuvir	2017/9/20	Single	J	Oral common-release	Imported	No	/	/
235	Riociguat	2017/9/20	Single	C	Oral common-release	Imported	No	/	/
236	Nintedanib	2017/9/20	Single	L	Oral common-release	Imported	Yes	2021/3/9	3.5
237	Empagliflozin	2017/9/20	Single	A	Oral common-release	Imported	Yes	2020/8/3	2.9
238	Telmisartan and Amlodipine	2017/9/20	Compound	C	Oral common-release	Imported	Yes	2021/6/8	3.7
239	Sofosbuvir	2017/9/20	Single	J	Oral common-release	Imported	Yes	2020/3/19	2.5
240	Macitentan	2017/9/29	Single	C	Oral common-release	Imported	No	/	/
241	Canagliflozin	2017/9/29	Single	A	Oral common-release	Imported	Yes	2019/12/25	2.2
242	Mirabegron	2017/9/29	Single	G	Other	Imported	Yes	2021/4/13	3.5
243	Lixisenatide	2017/9/29	Single	A	Solution	Imported	No	/	/
244	Diquafosol	2017/10/20	Single	S	Other	Imported	No	/	/
245	Vortioxetine	2017/11/21	Single	N	Oral common-release	Imported	Yes	2021/7/20	3.7
246	Rivastigmine	2017/11/21	Single	N	Other	Imported	No	/	/
247	Indacaterol and Glycopyrronium Bromide	2017/12/28	Compound	R	Other	Imported	No	/	/
248	Eltrombopag	2017/12/28	Single	B	Oral common-release	Imported	No	/	/
249	Umeclidinium Bromide and Vilanterol Trifenatate	2018/3/12	Compound	R	Other	Imported	No	/	/
250	Delamanid	2018/3/12	Single	J	Oral common-release	Imported	No	/	/
251	Raltegravir Potassium	2018/4/12	Single	J	Other	Imported	No	/	/
252	Lxazomib	2018/4/12	Single	L	Oral common-release	Imported	No	/	/
253	Glycopyrronium Bromide	2018/4/16	Single	R	Other	Imported	Yes	2020/10/9	2.5
254	Etonogestrel and Ethinylestradiol	2018/4/28	Compound	G	Other	Imported	No	/	/
255	Perindopril and amlodipine	2018/4/28	Compound	C	Oral common-release	Imported	No	/	/
256	Elbasvir and Grazoprevir	2018/4/28	Compound	J	Oral common-release	Imported	No	/	/
257	Anlotinib	2018/5/8	Single	L	Oral common-release	Domestic	No	/	/
258	Sofosbuvir and velpatasvir	2018/5/23	Compound	J	Oral common-release	Imported	No	/	/
259	Albuvirtide	2018/5/23	Single	J	Solution	Domestic	No	/	/
260	Ceritinib	2018/5/31	Single	L	Oral common-release	Imported	No	/	/
261	Danoprevir	2018/6/8	Single	J	Oral common-release	Domestic	No	/	/

262	Rotigotine	2018/6/8	Single	N	Oral common-release	Imported	No	/	/
263	Darunavir and Cobicistat	2018/6/19	Compound	J	Oral common-release	Imported	No	/	/
264	Tiotropium Bromide and Olodaterol	2018/7/18	Compound	R	Other	Imported	No	/	/
265	Teriflunomide	2018/7/18	Single	L	Oral common-release	Imported	No	/	/
266	Perfluorobutane Microspheres	2018/7/31	Single	V	Solution	Imported	No	/	/
267	Elvitegravir, Cobicistat, Emtricitabine and Tenofovir Alafenamide	2018/7/31	Compound	J	Oral common-release	Imported	No	/	/
268	Fluticasone and Vilanterol	2018/7/31	Compound	R	Other	Imported	No	/	/
269	Palbociclib	2018/7/31	Single	L	Oral common-release	Imported	Yes	2020/12/23	2.4
270	Alectinib	2018/8/12	Single	L	Oral common-release	Imported	No	/	/
271	Pyrotinib	2018/8/12	Single	L	Oral common-release	Domestic	No	/	/
272	Olaparib	2018/8/22	Single	L	Oral common-release	Imported	No	/	/
273	Lenvatinib	2018/9/4	Single	L	Oral common-release	Imported	Yes	2021/7/20	2.9
274	Fruquintinib	2018/9/4	Single	L	Oral common-release	Domestic	No	/	/
275	Degarelix	2018/9/11	Single	L	Solution	Imported	No	/	/
276	Buprenorphine and Naloxone	2018/9/11	Compound	N	Oral common-release	Imported	No	/	/
277	Olodaterol	2018/10/15	Single	N	Other	Imported	No	/	/
278	Rasburicase	2018/10/15	Single	V	Solution	Imported	No	/	/
279	Tenofovir alafenamide	2018/11/8	Single	J	Oral common-release	Imported	Yes	2020/10/15	1.9
280	Ledipasvir and Sofosbuvir	2018/11/21	Compound	J	Oral common-release	Imported	No	/	/
281	Emtricitabine and Tenofovir	2018/11/21	Compound	J	Oral common-release	Imported	Yes	2021/10/19	2.9
282	Lacosamide	2018/11/21	Single	N	Oral common-release	Imported	Yes	2019/1/25	0.2
283	Melphalan	2018/11/30	Single	L	Solution	Imported	No	/	/
284	Plerixafor	2018/11/30	Single	L	Solution	Imported	No	/	/
285	Selexipag	2018/12/7	Single	B	Oral common-release	Imported	No	/	/
286	Posaconazole	2018/12/7	Single	J	Other	Imported	Yes	2021/1/26	2.1
287	Bendamustine	2018/12/17	Single	L	Solution	Imported	Yes	2019/12/11	1.0
288	Roxadustat	2018/12/17	Single	B	Oral common-release	Domestic	No	/	/
289	Amlodipine and Folic Acid	2018/12/17	Compound	C	Oral common-release	Domestic	No	/	/
290	Dienogest	2018/12/21	Single	G	Oral common-release	Imported	Yes	2021/6/1	2.4
291	Edoxaban	2018/12/25	Single	B	Oral common-release	Imported	No	/	/
292	Linacotide	2019/1/9	Single	A	Oral common-release	Imported	No	/	/
293	Lurasidone	2019/1/24	Single	N	Oral common-release	Imported	Yes	2021/4/27	2.3
294	Metformin and Empagliflozin	2019/2/1	Compound	A	Oral common-release	Imported	Yes	2021/6/1	2.3
295	Sitafloxacin	2019/2/1	Single	J	Oral common-release	Imported	Yes	2021/6/25	2.4
296	Tedizolid	2019/2/22	Single	J	Oral common-release	Imported	No	/	/
297	Nusinersen	2019/2/28	Single	M	Solution	Imported	No	/	/
298	Polyethylene Glycol Loxenatide	2019/5/5	Compound	A	Solution	Domestic	No	/	/
299	Dacomitinib	2019/5/15	Single	L	Oral common-release	Imported	No	/	/

300	Glecaprevir and Pibrentasvir	2019/5/17	Compound	J	Oral common-release	Imported	No	/	/
301	Ceftazidime and Avibactam	2019/5/21	Compound	J	Solution	Imported	Yes	2021/9/30	2.4
302	Benvitimod	2019/5/31	Single	D	Other	Domestic	No	/	/
303	Baricitinib	2019/6/24	Single	L	Oral common-release	Imported	No	/	/
304	Carrimycin	2019/6/24	Single	J	Oral common-release	Domestic	No	/	/
305	Brinzolamide and Brimonidine	2019/7/4	Compound	S	Other	Imported	No	/	/
306	Fingolimod	2019/7/12	Single	L	Oral common-release	Imported	No	/	/
307	Eribulin	2019/7/12	Single	L	Solution	Imported	No	/	/
308	Garenoxacin	2019/7/26	Single	J	Oral common-release	Imported	No	/	/
309	Emtricitabine, Tenofovir Alafenamide and Bictegravir	2019/8/2	Compound	J	Oral common-release	Imported	No	/	/
310	Netupitant and Palonosetron Hydrochloride	2019/8/2	Compound	A	Oral common-release	Imported	No	/	/
311	Trifluridine and Tipiracil	2019/8/29	Compound	L	Oral common-release	Imported	Yes	2020/12/29	1.3
312	Apalutamide	2019/9/5	Single	L	Oral common-release	Imported	No	/	/
313	Clindamycin Phosphate and Benzoyl Peroxide	2019/9/29	Compound	D	Other	Imported	No	/	/
314	Perampanel	2019/9/29	Single	N	Oral common-release	Imported	No	/	/
315	Sodium Oligomannate	2019/11/2	Single	N	Oral common-release	Domestic	No	/	/
316	Fluticasone, Umeclidinium Bromide and Vilanterol	2019/11/4	Compound	R	Other	Imported	No	/	/
317	Enzalutamide	2019/11/20	Single	L	Oral common-release	Imported	Yes	2021/8/25	1.8
318	Flumatinib	2019/11/22	Single	L	Oral common-release	Domestic	No	/	/
319	Sofosbuvir, Velpatasvir and Voxilaprevir	2019/12/18	Compound	J	Oral common-release	Imported	No	/	/
320	Trametinib	2019/12/18	Single	L	Oral common-release	Imported	No	/	/
321	Dabrafenib	2019/12/18	Single	L	Oral common-release	Imported	No	/	/
322	Vonoprazan	2019/12/18	Single	A	Oral common-release	Imported	No	/	/
323	Budesonide, Glycopyrronium Bromide and Formoterol	2019/12/23	Compound	R	Other	Imported	No	/	/
324	Umeclidinium Bromide	2019/12/26	Single	R	Other	Imported	No	/	/
325	Remimazolam	2019/12/26	Single	N	Solution	Domestic	Yes	2020/7/16	0.6
326	Niraparib	2019/12/26	Single	L	Oral common-release	Domestic	No	/	/
327	Sodium Zirconium Cyclosilicate	2019/12/30	Single	V	Other	Imported	No	/	/
328	Tafamidis	2020/2/5	Single	N	Oral common-release	Imported	No	/	/
329	Tafamidis Meglumine	2020/2/5	Single	N	Oral common-release	Imported	No	/	/
330	Coblopasvir	2020/2/11	Single	J	Oral common-release	Domestic	No	/	/
331	Bencycloquidium Bromide	2020/3/17	Single	R	Other	Domestic	No	/	/
332	Almonertinib	2020/3/17	Single	L	Oral common-release	Domestic	No	/	/
333	Avatrombopag	2020/4/14	Single	B	Oral common-release	Imported	No	/	/
334	Neratinib	2020/4/27	Single	L	Oral common-release	Imported	No	/	/

335	Siponimod	2020/5/7	Single	L	Oral common-release	Imported	No	/	/
336	Glycopyrronium Bromide and Formoterol	2020/5/12	Compound	R	Other	Imported	No	/	/
337	Deutetrabenazine	2020/5/12	Single	N	Oral common-release	Imported	No	/	/
338	Zanubrutinib	2020/6/2	Single	L	Oral common-release	Domestic	No	/	/
339	Ravidasvir	2020/7/29	Single	J	Oral common-release	Domestic	No	/	/
340	Ertugliflozin	2020/7/29	Single	A	Oral common-release	Imported	No	/	/
341	Crisaborole	2020/7/29	Single	D	Other	Imported	No	/	/
342	Edaravone and Dexborneol	2020/7/29	Single	N	Solution	Domestic	No	/	/
343	Radium[223Ra] chloride	2020/8/26	Single	V	Solution	Imported	No	/	/
344	Pralatrexate	2020/8/31	Single	L	Solution	Imported	No	/	/
345	Ceftobiprole Medocaril	2020/10/27	Single	J	Solution	Imported	No	/	/
346	Ensartinib	2020/11/17	Single	L	Oral common-release	Domestic	No	/	/
347	Doravirine	2020/11/24	Single	J	Oral common-release	Imported	No	/	/
348	Venetoclax	2020/12/2	Single	L	Oral common-release	Imported	No	/	/
349	Fluzoparib	2020/12/11	Single	L	Oral common-release	Domestic	No	/	/
350	Eldecalcitol	2020/12/11	Single	M	Oral common-release	Imported	No	/	/
351	Ciprofol	2020/12/11	Single	N	Solution	Domestic	No	/	/
352	Emitasvir	2020/12/21	Single	J	Oral common-release	Domestic	No	/	/
353	Orelabrutinib	2020/12/25	Single	C	Oral common-release	Domestic	No	/	/
354	Abemaciclib	2020/12/30	Single	L	Oral common-release	Imported	No	/	/
355	Surufatinib	2020/12/30	Single	L	Oral common-release	Domestic	No	/	/
356	Doravirine Lamivudine and Tenofovir Disoproxil Fumarate	2020/12/31	Compound	J	Oral common-release	Imported	No	/	/

Note: ¹ Code for the therapeutic areas: A, Alimentary Tract and Metabolism; B, Blood and Blood Forming Organs; C, Cardiovascular System; D, Dermatologicals; G, Genito Urinary System and Sex Hormones; H, Systemic Hormonal Preparations, Excl. Sex Hormones and Insulins; J, Antiinfectives For Systemic Use; L, Antineoplastic and Immunomodulating Agents; M, Musculo-Skeletal System; N, Nervous System; P, Antiparasitic Products, Insecticides and Repellents; R, Respiratory System; S, Sensory Organs; V, Various.

Table 2. Drug Characteristic Associated with the Generic Entry of New Small-molecule Drugs Approved in China Between 2003 and 2020.

Drug Characteristics (N=356)	Odds Ratio	Standard Error	95% Confidence Interval	P value
Approval year of new drugs				
2003-2005	Ref.			
2006-2008	0.977	0.470	0.381 2.507	0.962
2009-2011	1.029	0.468	0.422 2.509	0.950
2012-2014	0.393	0.181	0.159 0.971	0.043
2015-2017	0.154	0.071	0.062 0.381	<0.001
2018-2020	0.071	0.032	0.030 0.170	<0.001
Domestic or imported				
Domestic	Ref.			
Imported	23.664	15.557	6.524 85.838	<0.001
Number of active ingredients				
Single preparation	Ref.			
Compound preparation	0.599	0.222	0.290 1.236	0.166
Dosage forms				
Others	Ref.			
Oral common-release preparation	2.297	0.923	1.044 5.051	0.039
Injection	1.998	0.916	0.813 4.908	0.131
Therapeutic areas				
Others	Ref.			
Alimentary tract and metabolism	1.462	0.741	0.542 3.947	0.453
Cardiovascular system	1.309	0.672	0.479 3.579	0.600
Antiinfectives for system use	1.633	0.725	0.685 3.897	0.269
Antineoplastic and immunomodulating agents	1.557	0.672	0.668 3.630	0.305
Nervous system	3.363	1.615	1.312 8.621	0.012

Table 3. Drug Characteristics Associated with the Length of Market Exclusivity for New Small-molecule Drugs Approved in China Between 2003 and 2020.

Drug Characteristics (N=155)	Coefficients	Standard Error	95% Confidence Interval	P value
Approval year of new drugs				
2003-2005	Ref.			
2006-2008	1.197	0.188	0.881 1.628	0.250
2009-2011	1.048	0.168	0.766 1.435	0.769
2012-2014	0.844	0.164	0.576 1.235	0.382
2015-2017	0.550	0.109	0.373 0.810	0.002
2018-2020	0.283	0.057	0.190 0.420	<0.001
Domestic or imported				
Domestic	Ref.			
Imported	0.942	0.400	0.410 2.164	0.889
Number of active ingredients				
Single preparation	Ref.			
Compound preparation	1.277	0.229	0.898 1.816	0.173
Dosage forms				
Others	Ref.			
Oral common-release preparation	1.252	0.209	0.903 1.737	0.178
Injection	1.152	0.219	0.794 1.672	0.457
Therapeutic areas				
Others	Ref.			
Nervous system	0.735	0.121	0.532 1.015	0.062
Antineoplastic and immunomodulating agents	0.958	0.166	0.682 1.347	0.806
Cardiovascular system	0.702	0.148	0.464 1.062	0.094
Antiinfectives for system use	0.783	0.149	0.539 1.137	0.199
Alimentary tract and metabolism	0.846	0.175	0.565 1.268	0.418