



Use of Medications Withdrawn from International Market for Safety Concerns in CHINA

Session 3
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Introduction

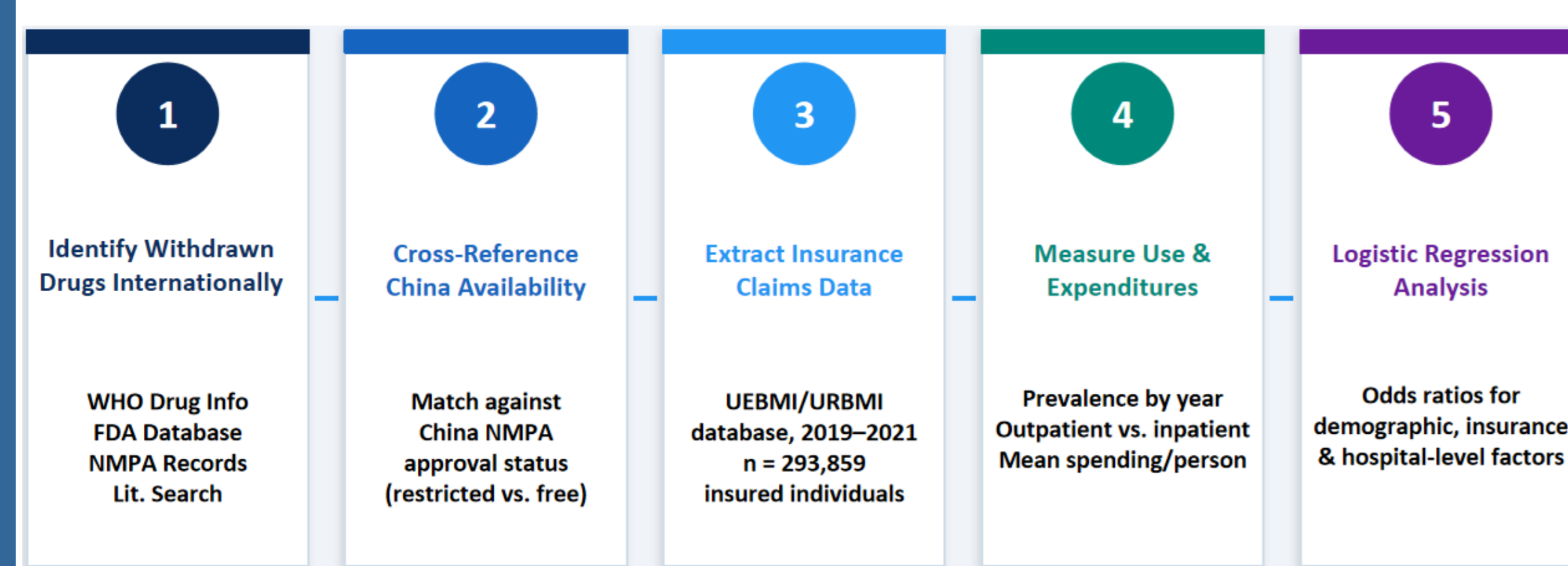
- Post-marketing evidence is crucial for identifying serious safety risks of approved drugs, and drugs may be withdrawn from the market when their risks exceed the clinical benefits.
- Withdrawal decisions vary widely by region. Among 121 safety withdrawals (1960–1999), 49.6% were global, while 42.1%, 5.0%, and 3.3% were regional (Europe, North America, Asia–Pacific).
- Withdrawn drugs may remain available elsewhere. Of 137 national essential medicines lists, 136 contained ≥1 withdrawn drug, >25% contained ≥10. Argentina had 17 such drugs; our China multi-city study found ≥21 withdrawn drugs still used.

Aim

Evidence on the extent of such use in China and the factors associated with continued prescribing is limited. This study examined the utilization of drugs withdrawn internationally for safety reasons within the Chinese healthcare system.

Methods — Study Design & Workflow

- Study Setting: Single Chinese province
- Design: Population-based retrospective cohort using real-world insurance claims
- Period: 2019–2021



Results

Table 1. Associations Between Patient and Institution Characteristics and Use of Withdrawn Drugs for Safety Concerns

Characteristics	Number of Prescriptions	Use of Withdrawn Drugs, n (%)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)*
Year				
2019	221,304	7186 (3.25)	1.0 (Ref)	1.0 (Ref)
2020	220,221	6642 (3.02)	0.92 (0.89, 0.95)***	0.87 (0.84, 0.91)***
2021	414,310	12017 (2.90)	0.90 (0.87, 0.93)***	0.84 (0.80, 0.87)***
Age, years				
< 65	581,597	16568 (2.85)	1.0 (Ref)	1.0 (Ref)
≥ 65	274,238	9277 (3.38)	1.04 (1.02, 1.07)**	0.90 (0.87, 0.94)***
Sex				
Female	404,964	12139 (3.00)	1.0 (Ref)	1.0 (Ref)
Male	450,871	13706 (3.04)	1.06 (1.03, 1.09)***	1.07 (1.04, 1.10)***
Race/ethnicity				
Han	727,676	22352 (3.07)	1.0 (Ref)	1.0 (Ref)
Miao/Dong/Buyi	45,394	1121 (2.47)	1.03 (0.96, 1.10)	1.02 (0.95, 1.09)
Others	82,765	2372 (2.87)	0.99 (0.94, 1.04)	0.95 (0.90, 1.00)
Working status				
Working	459,303	12103 (2.64)	1.0 (Ref)	1.0 (Ref)
Retired	396,532	13742 (3.47)	1.14 (1.11, 1.17)***	1.20 (1.16, 1.25)***
Occupation				
Agriculture and fishery workers	134,421	4332 (3.22)	1.0 (Ref)	1.0 (Ref)
Industrial and service workers	136,488	4076 (2.99)	0.94 (0.90, 0.99)*	0.94 (0.90, 0.99)*
Public sector employees	413,739	12333 (2.98)	1.02 (0.98, 1.06)	0.99 (0.95, 1.03)
Professionals	171,187	5104 (2.98)	0.95 (0.90, 0.99)*	0.96 (0.92, 1.01)
Insurance				
No additional subsidy	687,912	19624 (2.85)	1.0 (Ref)	1.0 (Ref)
With subsidy	167,923	6221 (3.70)	1.11 (1.08, 1.15)***	1.16 (1.12, 1.20)***
In-province visit				
Yes	853,142	25781 (3.02)	1.0 (Ref)	1.0 (Ref)
No	2,693	64 (2.38)	1.76 (1.25, 2.46)**	1.22 (0.87, 1.72)
Healthcare institution				
Tertiary	373,829	15635 (4.18)	1.0 (Ref)	1.0 (Ref)
Secondary	274,037	6881 (2.51)	0.99 (0.87, 1.14)	0.96 (0.84, 1.10)
Primary or others	207,969	3329 (1.60)	0.36 (0.31, 0.42)***	0.34 (0.29, 0.40)***
Public or private institution				
Public	728,957	22869 (3.14)	1.0 (Ref)	1.0 (Ref)
Private	126,878	2976 (2.35)	1.02 (0.92, 1.12)	1.16 (1.05, 1.28)**
General/specialized				
Specialized	59,858	1733 (2.90)	1.0 (Ref)	1.0 (Ref)
General	795,977	24112 (3.03)	1.05 (0.90, 1.21)	1.20 (1.04, 1.39)**

Notes: *Adjusted model included calendar year, age, sex, race/ethnicity, working status, occupation, insurance, whether or not in-province visit, types of healthcare institution, and city. *p<0.05, **p<0.01, ***p<0.001.
Abbreviations: CI, confidence interval; OR, odds ratio.

Figure 1. Trends in Withdrawn Drug Use (2019-2021)

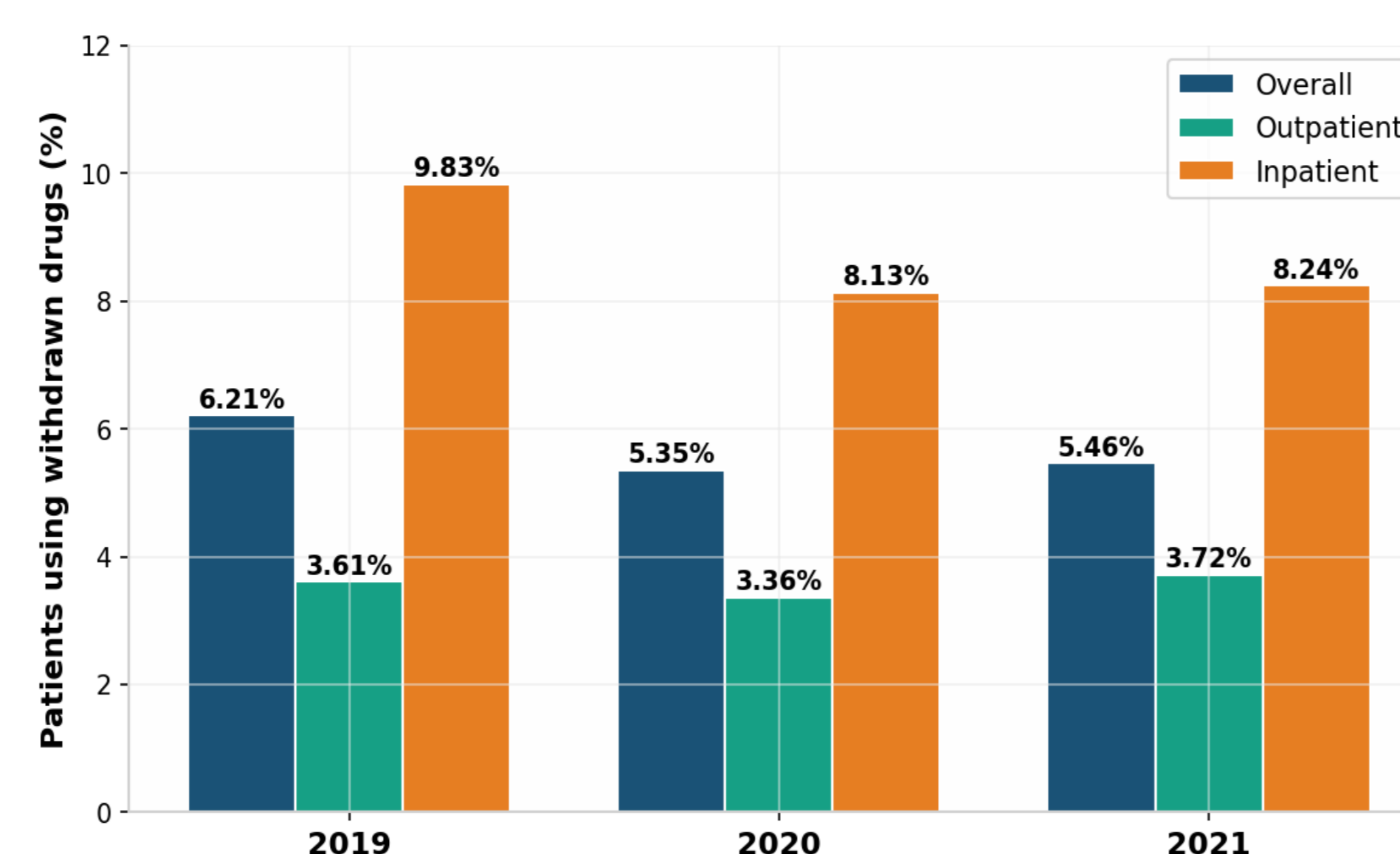


Figure 2. Expenditure on Withdrawn Drugs (2019-2021)

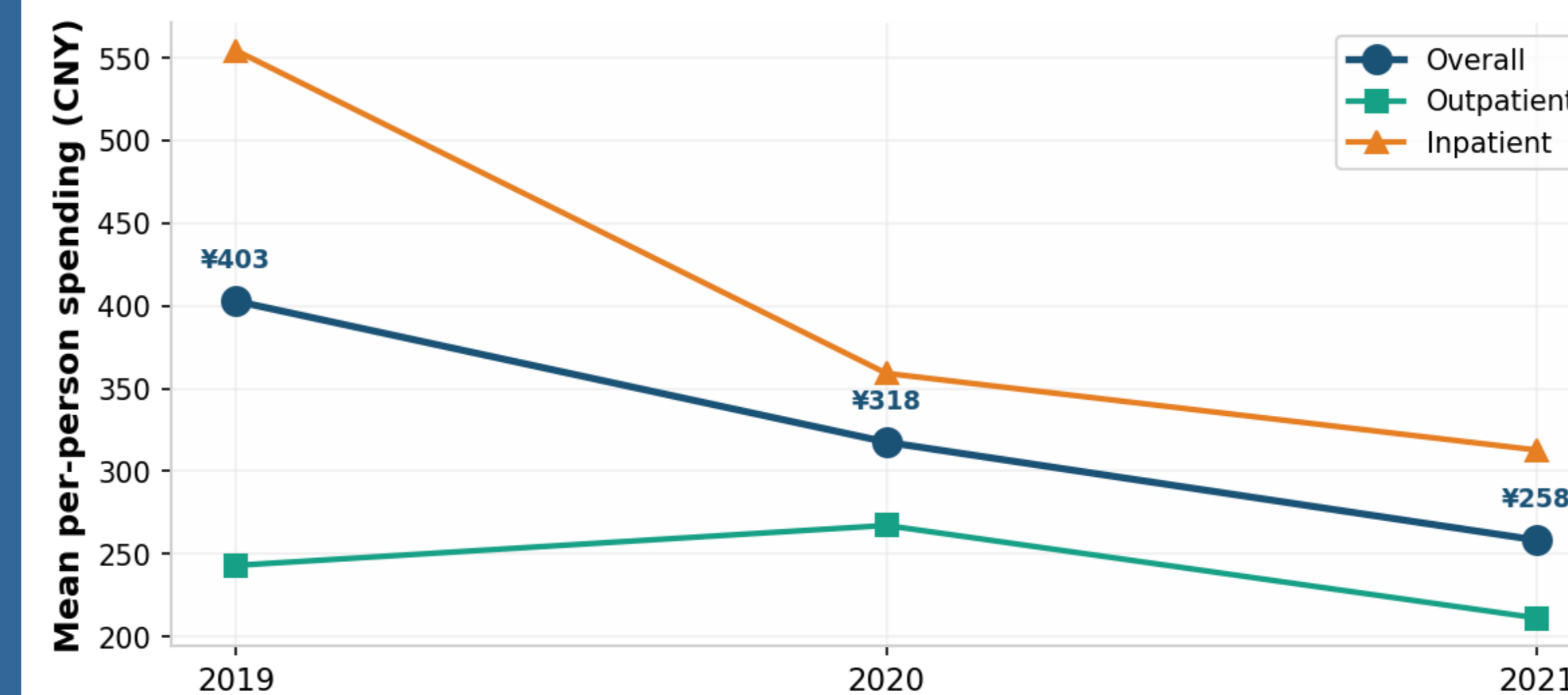


Figure 3. Proportion of Use by Drug Class (%)

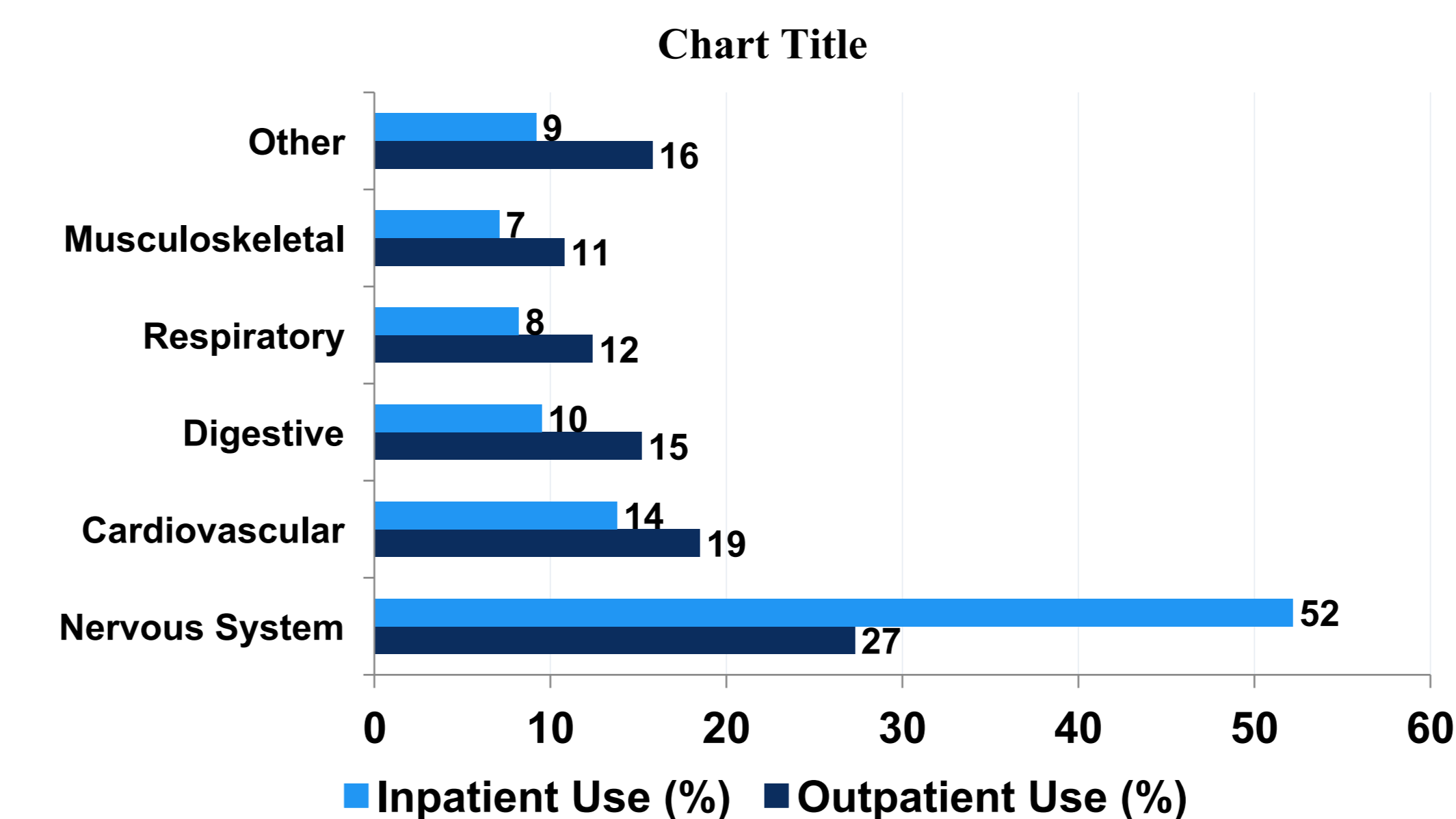


Figure 4. Expenditure Share by Class

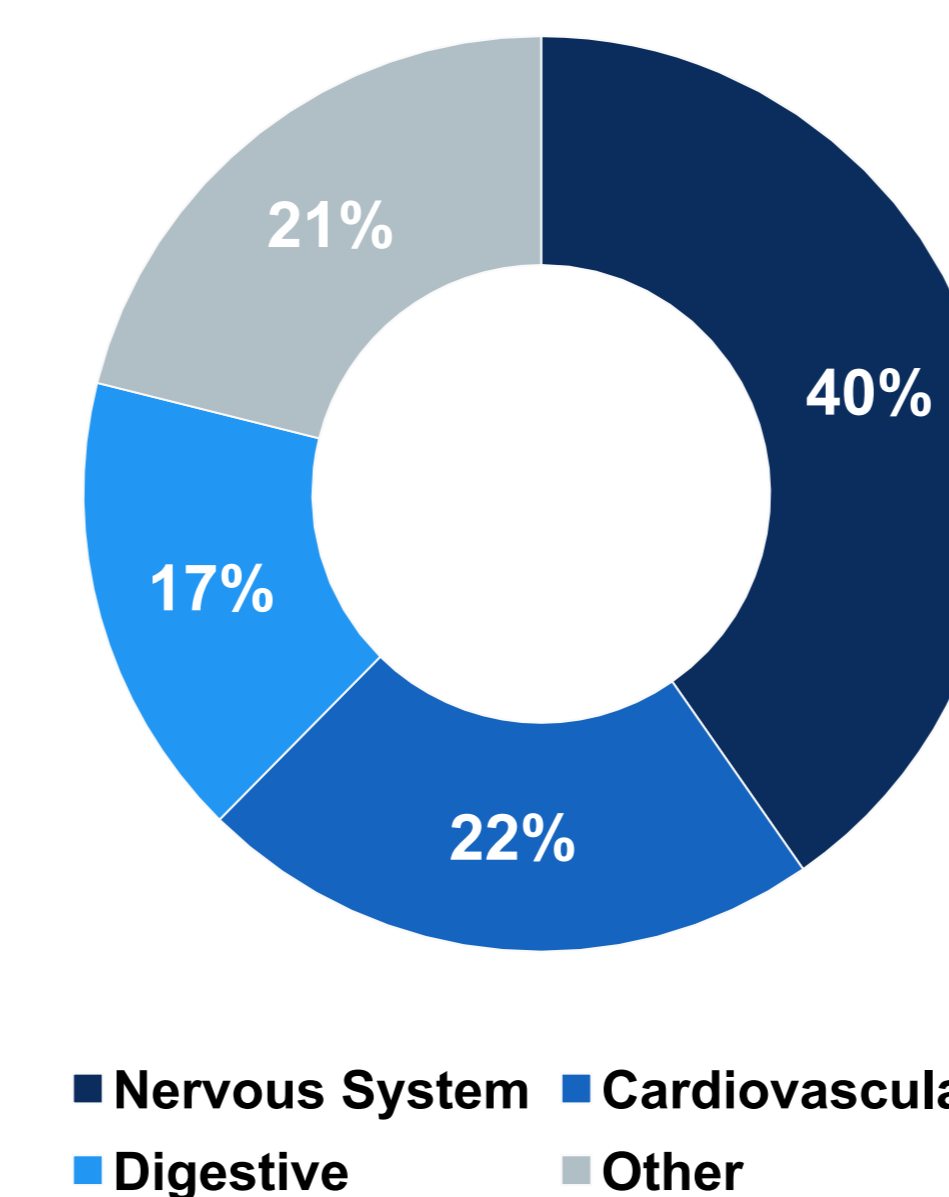


Figure 5. Top 10 drugs by Users in 2019 and 2021

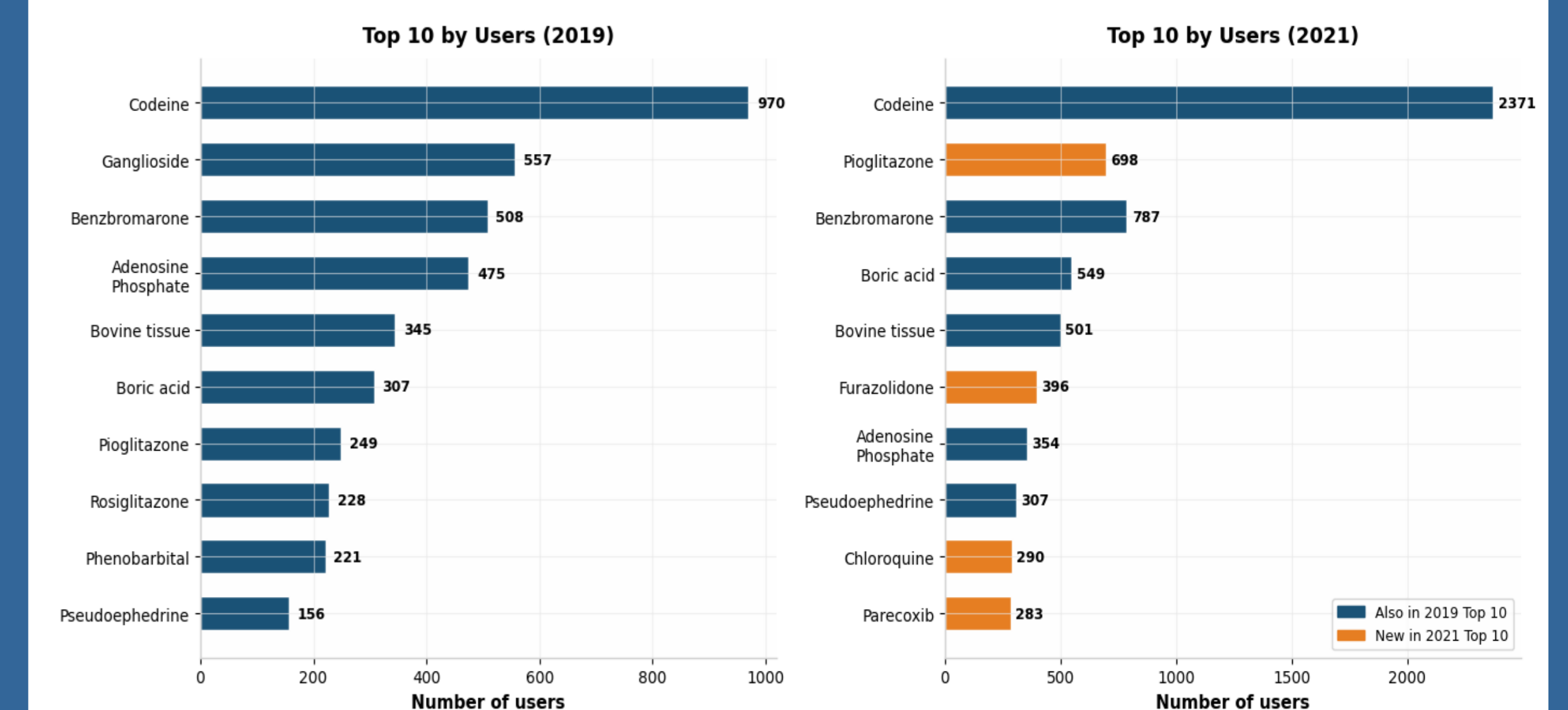
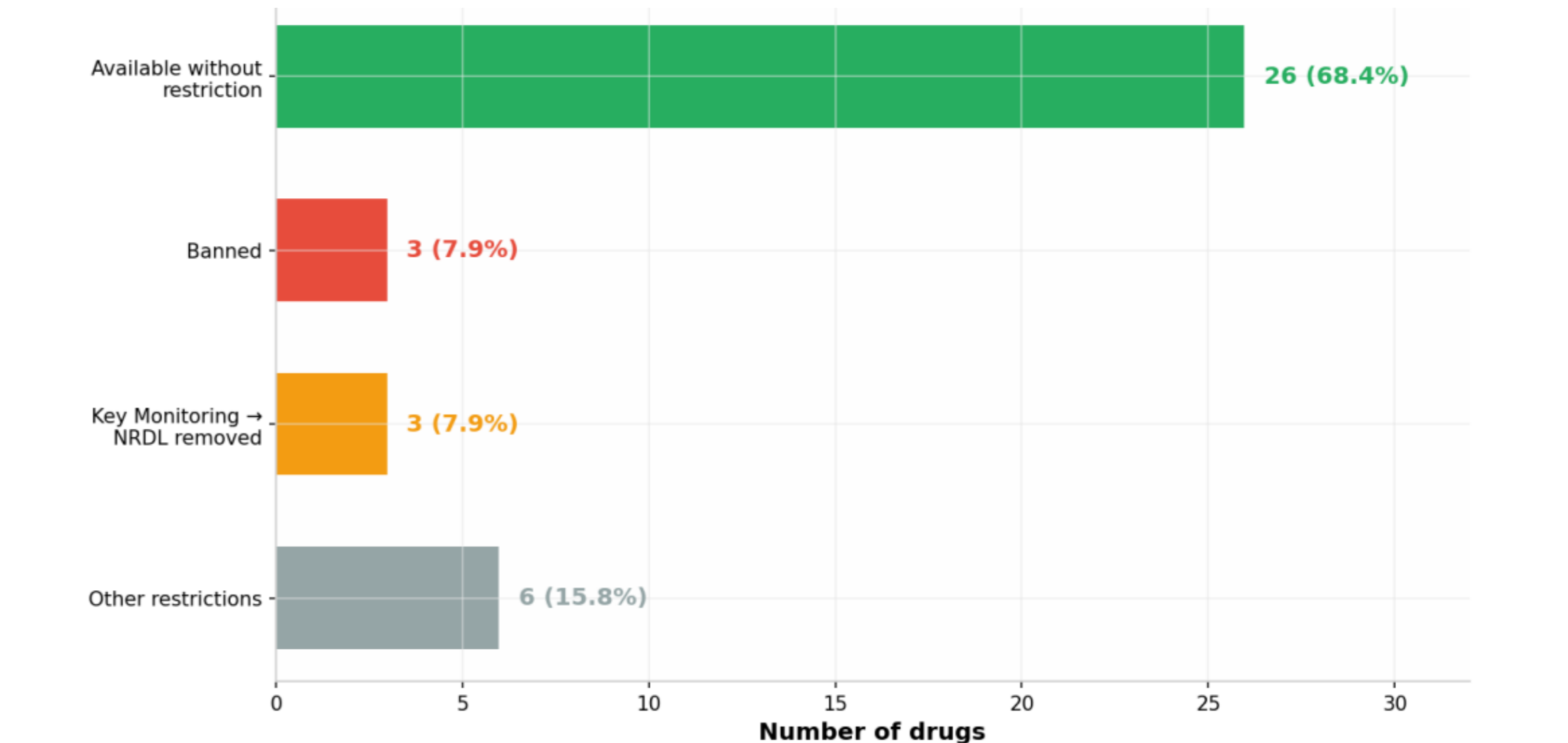


Figure 6. Regulatory Status of 38 Withdrawn Drugs in China (2019-2021)



Conclusion

- This study identified 38 internationally safety-withdrawn drugs still in clinical use domestically.
- National drug regulation shall be aligned with global safety evidence.
- Oversight of rational clinical prescribing needs to be enhanced.

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