

Trends in Single Source Generic Product Availability

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Background

- Single source generics (SSGs) are generic drugs produced by a single manufacturer
- Designation as a SSG may be at a single point in time or over the lifetime of the product
- Might expect price increases due to lack of competition
- Might expect drug shortages due to single manufacturer
- Uncertainty about the prevalence of SSGs and characteristics of these long-time SSG products

Objectives

- To quantify the prevalence of SSG products over the past 3 decades
- To characterize the long-time SSG products

Methods

- Used US Food and Drug Administration's Orange Book (accessed June 2017) to identify generic product approvals; Abbreviated New Drug Applications (ANDAs)
- Defined Single Source Generic (SSG) as a unique ingredient and route product having a single applicant during period of interest (Jan 1, 1982 – June 5, 2017)
- Removed products discontinued at anytime during study period
- Linked combination of ingredient and route to therapeutic groups and classes as defined in Truven Health Analytics Red Book™
- Characterized products by approval date, route, and therapeutic class

Examples of SSGs:

These are two different SSGs

1. Adapalene Cream; Topical 0.1% FOUGERA PHARMS
2. Adapalene Solution; Topical 0.1% CALL INC

This is one SSG

1. Aprepitant Capsule; Oral 125MG SANDOZ
1. Aprepitant Capsule; Oral 40MG SANDOZ
1. Aprepitant Capsule; Oral 80MG SANDOZ

Results

Approved products in Orange Book from January 1, 1982 to June 5, 2017
N=33,254

Products with ANDA submissions (i.e. generics)
(excluded over-the-counter products)
N=23,592

Unique products (defined as unique ingredient-route combination)
N=10,744

Products with a single manufacturer during 1982-2016
N=460 unique ingredient-product pairs (disregarding strength differences)

Products with a single manufacturer during 1982-2016 after exclusion of discontinued products
N= only 235 unique ingredient-product pairs (disregarding strength differences and discontinuations)

Acknowledgements

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Figure 1. Characterizing Approval Dates

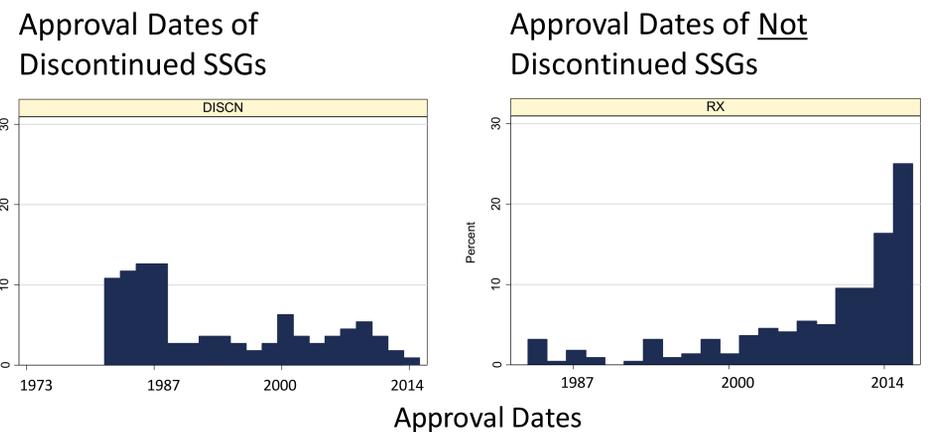


Table 1. High prevalence classes (non-discontinued SSGs)

Therapeutic Class	Count	Percent of Total (%)	Example (drug in class)
Antivirals	16	7.55	Efavirenz, tablet
Antiinflammatories, Skin & Combinations	12	5.66	Flurandrenolide ointment
Antibiotics, Miscellaneous	7	3.3	Linezolid, for suspension
Analgesic /Antipyretic, nonstr/Antiinflam	6	2.83	Naproxen, suspension
Psychotherapeutic/Antipsychotic	6	2.83	loperidone, tablet

Table 2. Over-represented Routes (non-discontinued SSGs)

Route	All products		Single source generic		Ratio of Percentages
	Count	Percentage	Count	Percentage	
Aerosol, foam; topical	11	0.28	4	1.72	6.14
For solution, tablet, delayed release; oral	1	0.03	1	0.43	14.3
For solution; topical	3	0.08	1	0.43	5.38
For suspension, delayed release; oral	4	0.1	2	0.86	8.60
Gel; vaginal	2	0.05	1	0.43	8.60
Granule, delayed release; oral	1	0.03	1	0.43	14.3
Injectable; intravenous, subcutaneous	2	0.05	1	0.43	8.60
Injectable; spinal	2	0.05	1	0.43	8.60
Ointment; transdermal	1	0.03	1	0.43	14.3
Pellet; implantation	2	0.05	1	0.43	8.60
Solution, metered; transdermal	1	0.03	1	0.43	14.3
Solution; nasal	4	0.1	2	0.86	8.60
Solution; perfusion, cardiac	1	0.03	1	0.43	14.3
Spray, metered; sublingual	1	0.03	1	0.43	14.3
Spray; nasal	3	0.08	2	0.86	10.8

Table 3. Over-represented Classes (SSGs not discontinued)

Therapeutic Class	All products*		Single source generic		Ratio of Percentages
	Count	Percentage	Count	Percentage	
Cholelitholytic Agents	1	0.04	1	1.89	47.2
Enzyme Inhibitors	1	0.04	1	1.89	47.2
Antimanic Agents	4	0.14	1	5.66	40.4
Cardiac Function,	1	0.04	1	1.42	35.5
Radiopharmaceuticals/Antineoplastic	1	0.04	1	0.94	23.5
Quinolones	5	0.18	2	2.83	15.7
Cell Stim/Proliferant Skin/Muc.membrane	2	0.07	4	0.94	13.4
Antineoplastic Adjunct Agents	1	0.04	1	0.47	11.8
Molecular Targeted Therapy	1	0.04	1	0.47	11.8
Phosphodiesterase Inhibitors	1	0.04	3	0.47	11.8
Antiinfective, Scabic/Pediculic	4	0.14	1	1.42	10.1
Leukotriene Modifiers	3	0.11	2	0.94	8.6
Benzodiazepines	27	0.95	1	7.55	8.0
Antidiabetic Agents, Misc	8	0.28	3	1.89	6.8
Antineoplastic Agent, Misc	2	0.07	1	0.47	6.7
Thyroid Function	2	0.07	1	0.47	6.7

Limitations

- Product discontinuation dates are not available in Orange Book
- Focus on SSGs does not acknowledge *limited* competition products (i.e., products with 1 or 2 competitors)

Conclusions

- Many SSGs were discontinued during the study period (conceivably due to competitors in *product class*)
- SSGs are over represented among product routes when therapeutic equivalence is challenging to demonstrate (e.g., oral vs topical)
- Therapeutic classes over-represented by SSGs suggests need for regulatory attention, unless therapeutic substitution is prevalent