

The Top Prescription Drugs of 2012 Globally: Biologics Dominate, But Small Molecule CNS Drugs Hold on to Top Spots

IMS Health recently released data on the top prescription drugs globally.¹ As we have done the previous three years, we are summarizing the key statistics.^{2–4} Global sales for prescription drugs reached \$856.1 billion in 2012, marking a 1.8% increase over 2011; however, this marks a steady decline over the last 5 years, where sales typically increased at ~5% annually.¹ Similarly, sales in the United States were ~\$330 billion, representing little growth over the previous year. Major patent expirations in 2011 had tremendous impact on pharmaceutical sales in 2012.^{1,4,5} Notably, Lipitor 1, the top selling drug for the past 8 years, fell to generic competition at the end of 2011, and lost the number 1 spot for the first time, falling to number 14 (\$5.1 billion) and losing 60.7% of its 2011 global sales (\$12.9 billion)! A similar situation befell the antipsychotic Seroquel 2, falling from number 7 in 2011 to number 41 in 2012 (Figure 1).¹ When reviewing the top 10 global products in terms of sales in 2012, it bears little resemblance to the same list in 2011.^{1,4} Five of the top 10 prescription drugs in 2012 are biologics (Table 1), and of the five small molecule therapeutics two are CNS: the antipsychotic Abilify 3 landed at number 7 (\$7.0 billion) and Cymbalta 4 held onto the number 10 position (\$5.8 billion). The statin Crestor 5 saw a 3% increase in 2012 sales to land at number 3 (\$8.3 billion), and the asthma/COPD therapeutic Advair (fluticasone 6/salmeterol 7) claimed the top position with \$8.9 billion in 2012 global sales. Nexium rounded out the top selling small molecule prescription drugs with 2012 sales of \$7.5 billion (number 4), a 7.2% decrease from 2011.¹ The remaining five drugs in the top 10 are biologics: AbbVie's Humira (monoclonal antibody for TNF α , number 2, \$8.5 billion), Amgen's Enbrel (monoclonal antibody for TNF α number 5, \$7.5 billion), Johnson & Johnson/Merck's Remicade (monoclonal antibody for TNF α number 6, \$7.3 billion), Sanofi-Aventis' Lantus (long-acting basal insulin analogue number 8, \$6.6 billion), and IDEC's MabThera (chimeric monoclonal antibody for CD20 number 9, \$6.0 billion).¹ The list, as compiled by Drugs.com,² for United States prescription drug sales represents the same top 20 drugs, but in different overall rankings. In the United States, Nexium was number 1 (\$5.63 billion in sales), Abilify was 2 (\$5.60 billion in sales), Crestor ranked third (\$4.7 billion in sales), and Advair was fourth (\$4.6 billion in sales).

Abilify 3, developed by Otsuka and BMS, is a great example of increasing market size, and product sales, by winning approval for multiple indications to increase the number of patients treated and to potentially extend patent protection.^{1,5} Abilify began as a next generation atypical antipsychotic, but it is now approved for bipolar disorder, irritability with autistic disorder, expanded use for pediatric patients, and as an add-on to antidepressant treatment.^{1,5,7} Marketing also played a key role, with promotional spending on Abilify accounting for 38% (\$173 million) of antipsychotic market promotional spending in 2011. Combined, the growth of global sales of Abilify is remarkable. In 2008,

global sales for Abilify were \$3.5 billion, and 2009 witnessed a 31.9% growth to \$4.7 billion. Annually, growth averaged ~14% from 2010 to 2012, resulting in \$7 billion in global sales in 2012.¹ The United States patent on Abilify expires in October of 2014; however, a pediatric extension ensures that generic versions of Abilify will not be available until April of 2015.^{1,5,7} Thus, it will be interesting to watch the continued growth of this antipsychotic agent over the next two years.

The top therapeutic classes in 2012 varied widely from their rankings in 2011 (Table 2).^{1,4} Last year, oncology ranked number one, with global sales of \$61.6 billion, followed by pain (\$56.1 billion), antihypertensive (\$51.6 billion), antidiabetic (\$42.4 billion), and mental health (\$41.6 billion). Many therapeutic classes lost significant growth in 2012 due to patent expirations on major products, with platelet aggregation inhibitors losing 23.3%, lipid regulators losing 14.2%, and mental health losing 13.8%. Despite this negative news, HIV antivirals grew 10.2% (\$18.9 billion), autoimmune diseases grew a handsome 15.1% (\$27.8 billion), and both the anti-diabetic (\$42.4 billion) and cardiovascular (\$19.2 billion) classes grew >8%.¹

Due to all the patent expirations that impacted 2012 pharmaceutical sales, the rankings of the top global pharmaceutical companies was also dramatically different in 2012 than in 2011 (Table 3).^{1,4} Novartis captured the top position with global sales of \$50.7 billion, followed by Pfizer (\$46.9 billion), Merck & Co. (\$40.1 billion), Sanofi (\$37.7 billion), Roche (\$35 billion) and GSK (\$32 billion). Generic product maker Teva retained the 10th position with global sales of \$24.8 billion, while Lilly held number 11 (\$21.9 billion) and BMS came in 16th with \$13.5 billion in global sales.¹

IMS Health also forecasted the global pharmaceutical market size and growth by region for 2012–2016.¹ North America and Japan are forecasted to increase by only 1–4%, and Europe is projected to remain flat or with only modest gains (0–3%). However, Latin America, Asia, Africa, and Australia are forecasted to grow an impressive 10–13% over the next four years.¹ As patent costs for foreign filings and translations increase, these projections may be of value to drug discovery organizations in considering where to nationalize their intellectual property to ensure protection and full rights in these rapidly expanding markets.

Overall, CNS agents performed well in 2012, holding two spots in the top 10 global pharmaceutical products, and representing two of only five small molecule therapeutics in the top 10. Patent expirations and generic competition had a major impact on the top prescription drugs in 2012, with Lipitor being unseated from the number 1 spot for the first time in 8

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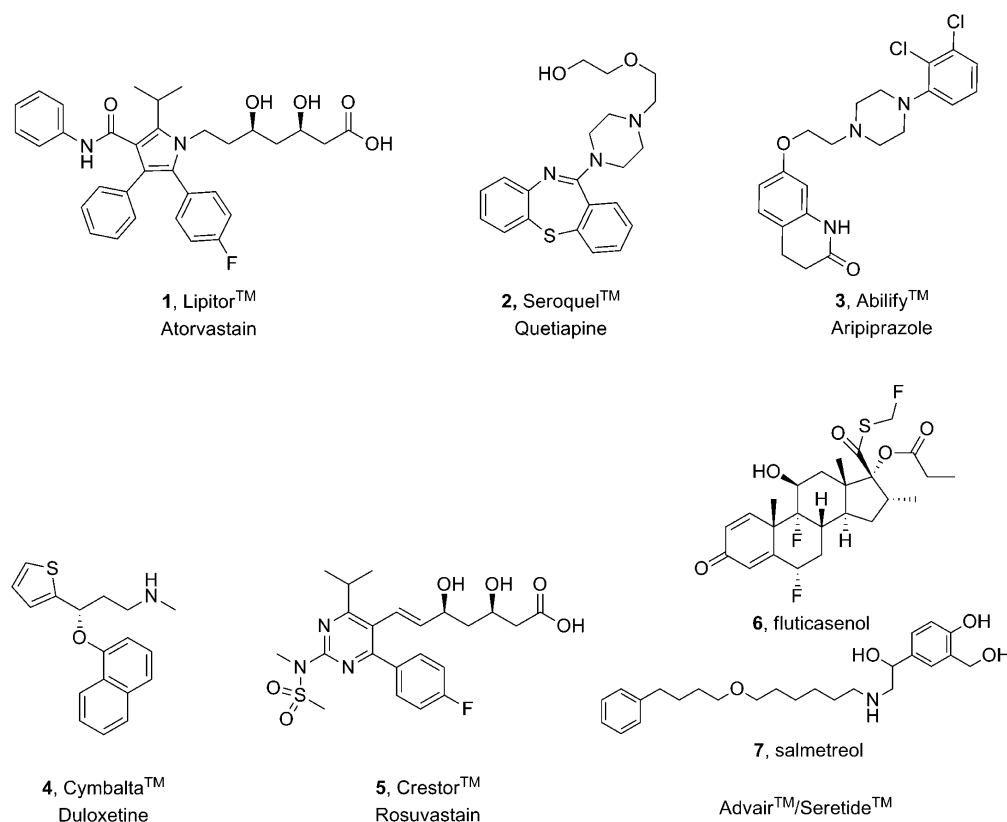


Figure 1. Structures of the top selling global small molecule drugs of 2012, and drugs that lost top positions due to patent expirations.

Table 1. Top 20 Prescription Drugs in Terms of Global Sales in 2012¹

rank	product	sales (US\$Bn)
1	Advair Diskus	8.9
2	Humira	8.5
3	Crestor	8.3
4	Nexium	7.5
5	Enbrel	7.5
6	Remicade	7.3
7	Abilify	7.0
8	Lantus	6.6
9	MabThera	6.0
10	Cymbalta	5.8
11	Avastin	5.4
12	Plavix	5.2
13	Spiriva	5.1
14	Liptior	5.1
15	Herceptin	5.0
16	Singulair	4.7
17	Lyrica	4.6
18	Copaxone	4.5
19	Glivec	4.3
20	Neulasta	4.3

years, and biologics capturing half of the top 10 spots. Moreover, forecasts suggest limited growth in the United States, Japan, and Europe through 2016, but massive growth in Latin America, Asia, Africa, and Australia. Undoubtedly, these emerging trends will lead to new patenting strategies with respect to foreign nationalization.

Craig W. Lindsley, Editor-in-Chief

Table 2. Top 10 Therapeutic Classes Globally in 2012¹

rank	therapeutic class	sales (US\$Bn)	% growth
1	oncology	61.6	+5.1
2	pain	56.1	+2.7
3	antihypertensive	51.6	-3.5
4	antidiabetic	42.4	+8.2
5	mental health	41.6	-13.8
6	respiratory	39.7	+1.4
7	antibacterial	38.8	-3.7
8	lipid regulators	33.6	-14.2
9	autoimmune disorders	27.8	+15.1
10	anti-ulcerants	26.0	-2.4

Table 3. Top 10 Global Pharmaceutical Corporations in 2012¹

rank	pharmaceutical company	sales (US\$Bn)
1	Novartis	50.7
2	Pfizer	46.9
3	Merck & Co.	40.1
4	Sanofi	37.7
5	Roche	35.0
6	GlaxoSmithKline (GSK)	32.7
7	AstraZeneca	31.9
8	Johnson & Johnson	27.9
9	Abbott (AbbVie)	26.7
10	Teva	24.8

DISCLOSURE

Views expressed in this editorial are those of the author and not necessarily the views of the ACS.

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