

R&D productivity - focus on quality not just quantity



The tally of new drugs approved each year in the US is often used as a measure of R&D productivity in the industry. However, a look at the sales performance of each year's cohort five years after launch paints another picture and suggests the measure for R&D success should focus on the quality of products approved, rather than just the quantity.

As the table below shows, collated from actual and forecast data by EvaluatePharma, the picture is not as gloomy as the downward trend seen in approvals, with 2008 promising a significant return to quality and quantity. It does confirm, however, that 2007, when only 22 NMEs and new biologics were approved, the lowest for two decades, was not one of the sector's best attempts in terms of volumes or sales potential.

Year	No. of NMEs Approved	No. of Biologicals Approved	Total NMEs + Biologicals	% Chg.	USA Sales 5th Post launch (\$bn)	% Chg.
2008 (projected)	31	4	35	+59%	9.8	+28%
2007	16	6	22	-24%	7.6	-41%
2006	18	11	29	+4%	12.8	+77%
2005	18	10	28	-26%	7.3	-50%
2004	31	7	38	+9%	14.6	+75%
2003	21	14	35	+35%	8.3	-35%
2002	17	9	26	-19%	12.8	+51%
2001	24	8	32	-3%	8.5	+15%
2000	27	6	33	-18%	7.4	+4%
1999	35	5	40	+3%	7.1	-48%
1998	30	9	39	-20%	13.5	+82%
1997	39	10	49	-21%	7.4	-52%
1996	53	9	62		15.5	

Last year the most notable approvals, according to consensus forecasts, are Tekturna, the Novartis and Speedel treatment for pulmonary hypertension, and Shire's ADHD drug Vyvanse. The two products are respectively forecast to be generating US sales of \$1.31bn and \$998m in 2012, five years down the line. However both have been subjected to significant downgrades since they were launched, and doubts remain over even these lowered expectations. The class of 2007 could therefore turn out to be even more of an underachiever.

Top 10 New Molecular Entities in 2007: ranked on 2012 US sales

Rank	Product	Company	Approved	2007 US Sales (\$m)	2012 US Sales (\$m)
1	Tekturna/Rasilez	Novartis	Mar 2007	34	1312
2	Vyvanse	Shire	Feb 2007	77	998
3	Letairis/Volibris	Gilead Sciences	Jun 2007	20	791
4	Tykerb	GlaxoSmithKline	Mar 2007	72	724
5	Bystolic	Forest Laboratories	Dec 2007	-	590
6	Isentress	Merck & Co	Oct 2007	29	506
7	Ixempra	Bristol-Myers Squibb	Oct 2007	15	404
8	Kuvan	BioMarin Pharmaceutical	Dec 2007	0	373
9	Torisel	Wyeth	May 2007	-	368
10	Soliris	Alexion Pharmaceuticals	Mar 2007	46	308
	Other			79	1261
	Total			373	7634

In the last decade 1999 was definitely bottom of the class in terms of value added, despite bringing a healthy-looking 40 new drugs to the market. That year Vioxx, Actos and Avandia were launched, contributing to a relatively paltry total of \$7.1bn five years post launch, impacted by the withdrawal of Vioxx in 2004 which lost about \$700m in revenue that year.

In 1996, the bumper year of the last decade, saw the approval of Lipitor, Zyprexa and Allegra, while another lucrative 12 months was 2004, which saw Avastin, Cymbalta, Lyrica and Spiriva get the green light.

For all the criticisms of the last couple of years, which has seen a steady decline in approval numbers, 2006 stands out for its relatively low approval rate but high sales success.

Merck & Co's Januvia and Gardasil shine in that class, and probably help explain the 39 % appreciation in the company's share price since, even considering the recent fall out from Vytarin.

So far 2008 is showing encouraging signs of a significant improvement on 2007 both in terms of quantity and quality. Five year sales forecasts for the class of 2008 are expected to grow by 28% to \$9.8bn, with a potential 35 new approvals. This however assumes that all new products currently filed with the FDA get the go-ahead, an unlikely scenario. Even risk-adjusting these figures by the industry standard of 5%, the industry's R&D productivity appears to have improved on last year, and could rank as the sixth most productive year in the last 13 years.

Top 10 New Molecular Entities in 2008: ranked on 2013 US sales

Rank	Product	Company	Approved / Approval by	2008 US Sales (\$m)	2013 US Sales (\$m)
1	Actemra	Roche	19 Sep 08	21	809
2	Pristiq	Wyeth	29 Feb 08	44	727
3	Effient	Eli Lilly	26 Jun 08	16	642
4	Cordaptive	Merck & Co	30 Apr 08	77	636
5	Milnacipran	Forest Laboratories	31 Oct 08	3	625
6	Promacta/Revolade	GlaxoSmithKline	01 Jul 08	3	621
7	Cimzia	UCB	22 Apr 08	9	447
8	Fiapta	Vanda Pharmaceuticals	25 Jul 08	-	398
9	Bridion	Schering-Plough	02 Jul 08	24	359
10	Recothrom	ZymoGenetics	17 Jan 08	40	346
	Other			288	4166
	Total			526	9775