Evaluate Vantage

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Friendly FDA ups number of NMEs

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The FDA's pace of new drug approvals last year – 43 when all biologicals are added in – has been highly praised throughout the industry. What is even more impressive is their quality.

Fifth-year sales forecasts for the class of 2012 equal $15.7bn. If achieved, those estimates would make drugs approved last year comparable to the class of 2004, a year that included such money-spinners as Avastin and Cymbalta. While it is still too soon to write an epitaph on the patent cliff, the launch of Eliquis, Stribild and Xtandi should be balm to investors who have been waiting for signs that R&D productivity is picking up (see tables).

Year	No. of NMEs approved	No. of biologicals approved (CDER + CBER)	Total NMEs + biologicals	% chg in total new products	US sales 5th-year post-approval ($bn)	% chg in value added
2012	31	12	43	+23%	15.7	+49%
2011	24	11	35	+35%	10.5	+4%
2010	15	11	26	-24%	10.1	+89%
2009	19	15	34	+10%	5.4	+6%
2008	21	10	31	+19%	5.0	+17%
2007	16	10	26	-10%	4.3	-52%
2006	18	11	29	+4%	8.9	+35%
2005	18	10	28	-26%	6.6	-55%
2004	31	7	38	+9%	14.8	+63%
2003	21	14	35	+35%	9.1	-28%
2002	17	9	26	-19%	12.7	+48%
2001	24	8	32	-3%	8.6	+13%
2000	27	6	33	-18%	7.6	+7%
Ten year average (02 - 11)	*20*	*11*	*31*	-	*8.7*	-
Current 5yr average (07-11)	*19*	*11*	*30*	-	*7.1*	-
Previous 5yr average (02-06)	*21*	*10*	*31*		*10.4*	-

After the fire

Following a wildfire, new life is quick to spring up, and the industry might be living through one of the biggest conflagrations it has seen. Drugs with combined sales of more than $30bn, including Plavix and Seroquel, fell

prey to generic competition last year and another $20bn are at risk this year (*Patent storm hits in 2012, February 8, 2012*).

Investors have conferred low or zero valuation on R&D pipelines for years as clinical and regulatory hurdles have grown and the costs of bringing a product to market have climbed. The period between 2005 and 2010 was a clear nadir, with the number of new products and their value lower than historical trends; it coincided with heightened safety worries in the wake of the withdrawal of Vioxx and reporting of Avandia's cardiovascular dangers.

Thus the quick pace of approvals last year – December alone saw eight, including Eliquis's three months before the deadline – as well as their expected value should be taken as an encouraging sign that the industry might be emerging from a challenging period.

Some credit is probably due to changes to the PDUFA law setting standards and deadlines for FDA action. The new version of the law that went into place last year adopts some specific procedures aimed at reducing first-cycle rejections and multiple application cycles. That there was no major drug-safety scandal in the past few years probably helped ensure that Congress did not seek to impose some onerous new conditions on the drug-approval process (*PDUFA V nears final act, May 31, 2012*).

However, the agency would not be able to approve the products if pipelines were empty, and the fact that approvals are matching those of the mid-1990s is a sign that pharma's innovation engine is beginning to fire on all cylinders once again.

Top 5 FDA approvals for NME drugs in 2012 (ranked on US

Rank	FDA approval date	Product	Generic name	Therapy category	Pharmacology class	Technology	Co
1	28/12/2012*	Eliquis	apixaban	Blood	Factor Xa inhibitor	Small molecule chemistry	Bris Squ
2	27/08/2012	Stribild	cobicistat; elvitegravir; emtricitabine; tenofovir disoproxil fumarate	Systemic Anti-infectives	Nucleoside reverse transcriptase inhibitor (NRTI), HIV integrase inhibitor & CYP3A inhibitor	Small molecule chemistry	Gile Tob
3	31/08/2012	Xtandi	enzalutamide	Oncology & Immunomodulators	Androgen receptor antagonist	Small molecule chemistry	Mec Pha
4	06/11/2012**	Xeljanz	tofacitinib citrate	Musculoskeletal	Janus kinase (JAK)-3 inhibitor	Small molecule chemistry	Pfiz
5	20/07/2012	Kyprolis	carfilzomib	Oncology & Immunomodulators	Proteasome inhibitor	Small molecule chemistry	Liga Pha Pha

*Approval came three months early; **approval delayed from August

The festive-period approval of Eliquis in stroke prevention was a big help not only in achieving the impressive approval numbers but also in establishing the class of 2012's value. The Bristol-Myers Squibb and Pfizer pill was awarded the best label in the new class of anticoagulants, and as such is expected to pull down more than $3bn in worldwide sales by 2018.

Despite the focus on genetic orphan diseases as a quick path to approval, high prices and huge sales, the road to blockbuster status still runs through many of the large indications: besides Eliquis, Gilead Sciences' Stribild is in HIV, Medivation's Xtandi is in prostate cancer, Pfizer's Xeljanz is in rheumatoid arthritis, and Onyx's Kyprolis is in multiple myeloma.

One of the reasons that pharma sales growth has been so slow has been a focus on "me-too" drugs. However,

it is interesting to note that of those top five drugs approved in 2012 three represent new or nearly-new mechanisms of action: Eliquis, Xtandi and Xeljanz.

It is still too soon to conclude that the dark days for industry productivity are at an end, but the signs are definitely growing. The current trends may need to be sustained for at least a couple more years before investors, chastened by the lessons of the patent cliff, drop their incredulous postures.

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