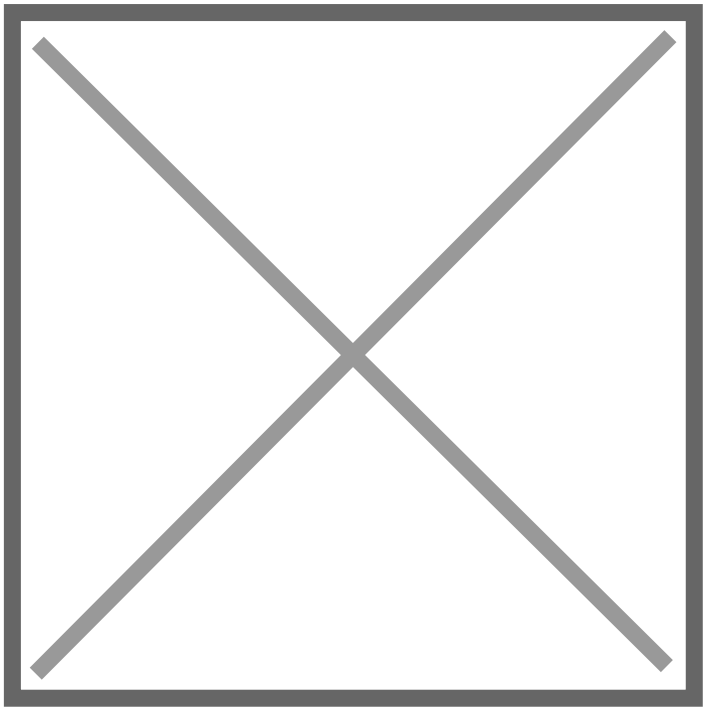
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FDA approvals for biotechs decline

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The US FDA approvals for biopharma products plunged in 2007.

Is the biotechnology running out of steam after many years of great growth in terms of new product development? This is the question on every analyst's mind after a just released study on the approvals of biopharmaceuticals in the last decade, done by Dr Ronald A Rader. For an industry used to getting approvals for close to two-dozen products every year, the year 2007 was dismal with the US government's Federal Drug Authority (FDA) approving only 11 biopharmaceutial products for marketing in the last 12 months.

It followed a dismal 2006 when only 10 biopharma products got the FDA approval. Biopharmaceuticals represent a class of pharma products that include recombinant proteins, monoclonal antibodies (mAbs) and some indications of existing drugs to treat various types of cancers.

BioPharma product approvals take a dip in the US

- FDA approvals of biopharmaceutical products have decreased in recent years. This includes recombinant proteins and monoclonal antibodies and cancer therapeutics.
- In the decade 1996-2005, there were an average of 16.6 approvals per year, while there were only 12 and 11 approvals in 2006 and 2007, respectively.
- 2007 was a particularly unproductive year. Besides a low level of novelty (with many products similar to prior products), all of the 2007 approvals combined are projected to have less than blockbuster ($1 billion per year) sales (not counting Mircera, which is barred from marketing due to patents), and none will significantly improve healthcare for a large number of patients. Only two recombinant proteins were approved in 2007, a level more typical of the 1980s.
- The low numbers of approvals in recent years are of particular concern, because a large number of products have been in the development pipeline.
- It is unclear why approvals have decreased and who, if anyone (FDA and/or industry), deserves the blame for this.
- Filings for a number of products are pending or expected. So, major increases in approvals are likely in 2008 and 2009.
- If biopharmaceutical approvals, their novelty and healthcare and economic impact remain at recent and, particularly, 2007 levels, the industry is headed for serious problems, potentially even economic collapse.
- (Source: Dr Ronald A Rader, author of Biopharmaceutical Products in the US and European Markets. The author is President, Biotechnology Information Institute, Rockville, Maryland, US. More details available at www.biopharma.com)

A comprehensive study on biopharmaceutical products in the US and European markets, analyzing the regulatory trends between 1995 and 2007 by Dr Rader, has appeared in the March 15, 2008 issue of Genetic Engineering and Biotechnology News (GEN).

Some analysts have blamed the cautious approach adopted by FDA in the wake of recent controversies leading to the withdrawal of several pharmaceutical products from the market after the discovery of unintended side-effects and even dozens of deaths.

However, Dr Rader notes that relatively few filings for biopharmaceuticals have been arbitrarily delayed, put on long-term hold or denied. Rather, it appears that fewer products are successfully making it through pivotal phase III trials.

Dr Rader reasons that FDA may well be slowing down and shifting its approval criteria to be more restrictive, but most of the biopharmaceuticals affected by FDA delays or denials had problems, usually not attaining their preset primary endpoints in pivotal trials or otherwise having problems with safety or efficacy.

The industry will be watching with bated breath the fate of nearly two dozen filings for regulatory approvals from the industry which are currently pending with the FDA. An equal number of filings are expected in 2008 too.

Dr Rader's study showed that the FDA approved an average of 16.6 products in the years between 1996 and 2005. The year 1997 was the best ever period for the biotech industry with FDA approvals for a record 23 products, which included 12 recombinant proteins and mAbs.

Most of the 11 approvals in 2007 were incremental advances, me-too products, and those with rather specialized indications. Besides a low level of novelty (with many products and their indications similar to those of prior products), none of the 2007 products are expected to significantly improve healthcare for large numbers of patients, emphasized Dr Rader.

The 2007 approval with by far the most potential impact, Mircera (pegylated recombinant erythropoietin--PEG-EPO), from Roche, will probably not be sold in the US for at least several years due to patent infringement issues. Without Mircera, a likely blockbuster, the projected market for all products approved in 2007 does not even attain blockbuster level (>$1 billion per year revenue). The low number of recombinant protein or mAb approvals in 2007 (only two) is more typical of the 1980s. And other than a formal approval for Epicel (cell cultured skin patches) from Genzyme, a product already marketed for 20 years, no established or mainstream US biotechnology company received an approval, with approvals primarily granted to large foreign and small, new entrant, US biotech companies.

Hardly any mAbs or cancer therapeutics was approved in recent years, despite seemingly endless hype about large numbers in development. No biopharmaceuticals were approved for cancer indications in 2007, only one was approved in 2006, and only one mAb received approval in both 2006 and 2007.

BioPharma products approved by FDA in 2008, 2007, and 2006				
Product	Brand	Approval (DD-MM-YY)	Company	Indication
2008				
Fibrin Sealant	Artiss	19/03/08	Baxter Healthcare	For use in attaching skin grafts onto burn patients
Interleukin-1 trap	Arcalyst	27/02/08	Regeneron Pharmaceuticals	For long term treatment of CAPS disorders
Antihemophilic factor	Xyntha	21/02/08	Wyeth	For hemophilia A
Somatropin	Accretropin	24/01/08	Cangene Corp.	For treatment of pediatric growth failure or short statur
Thrombin	Recothrom	17/01/08	ZymoGenetics	Halt bleeding from small blood vessels after surgery.
2007				
EPO, PEG	Mircera*, CERA	14/11/07	Hoffmann-La Roche	Treatment of anemia associated with chronic renal fail
Cultured epidermal autograft	Epicel	19/10/07	Genzyme	Treatment of wounds resulting from severe burns.
Influenza virus vaccine	AFLURIA	28/09/07	CSL	Prophylaxis against influenza
Smallpox vaccine	ACAM200	31/08/07	Acambis	Prophylaxis against smallpox
Thrombin	Evithrom	27/08/07	Omrix Biopharma	Control of bleeding
Fibrin Sealant	CryoSeal	26/07/07	Thermogenesis	Control of bleeding during liver surgery
Immune globulin	IGIV, Privigen	26/07/07	CSL BioPlasma	Treatment of primary immunodeficiency

Influenza vaccine	H5N1	17/04/07	Sanofi Pasteur	Active immunization against H5N1 influenza virus
Somatropin	Valtropin	19/04/07	Parexel	For treatment of growth
Protein C, plasma-derived	Ceprotin	27/03/07	Baxter Healthcare	Treatment of severe congenital Protein C deficiency
Complement C5 mAb	Soliris	06/03/07	Alexion Pharma	Treatment of paroxysmal nocturnal hemoglobinuria
Poly-4-hydroxybutyrate	TephaFLEX	12/02/07	Tepha	For use as surgical sutures
2006				
Albumin (Human)		17/10/06	Octapharma Pharma	Restoration and maintenance of blood volume
Influenza vaccine	FluLaval	05/10/06	GSK (ID Biomedical)	Active immunization against influenza
EGF receptor mAb	Vectibix	27/09/06	Amgen	For treatment of metastatic colorectal cancer
Iduronate-2-sulfatase	Elaprase	24/07/06	Shire (Transkaryotic)	For treatment of Hunter syndrome
VEGF mAb fAb	Lucentis	30/06/06	Genentech	For treatment of age-related macular degeneration
HPV vaccine	Gardasil	08/06/06	Merck	Prophylaxis against cervical cancer
Somatropin	Omnitrope	30/05/06	Sandoz	For treatment of growth hormone deficiency
Varicella virus vaccine	Zostavax	25/05/06	Merck	Prophylaxis against herpes zoster (shingles)
Glucosidase	Myozyme	28/04/06	Genzyme	For treatment of Pompe disease
Rotavirus vaccine	RotaTeq	03/02/06	Merck	Prophylaxis against rotavirus
Hepatitis B immune globulin	HepaGam B	27/01/06	Cangene	Post-exposure prophylaxis against hepatitis B virus
Insulin	Exubera	27/01/06	Pfizer	For the treatment of type 1 and type 2 diabetes
Immune globulin subcutaneous	Vivaglobin	09/01/06	ZLB Behring	For treatment of primary immunodeficiency

Note:

- Product may never be launched in the US due to infringement of patents held by Amgen (related lawsuit not yet fully resolved).

- Compiled by Dr Ronald A Rader from FDA filings

- Biopharmaceuticals are defined as pharmaceuticals inherently biological in nature manufactured using biotechnology (live organisms). This does not include small molecule or other drugs, but includes biopharmaceuticals irrespective of their regulation as biologics, drugs or medical devices.

Narayanan Suresh