

HDMA News Media Factsheet

Drug Shortages and Availability*

(Compiled from publicly available news sources)

Scope:

We use the term “shortage” inexactly; more specifically, we are describing some unavailability of a drug. “Shortage” defines a market demand for a drug that cannot be obtained easily through established channels either because it is no longer made, it is not made in sufficient quantities to meet expressed needs, or it is not available without demonstrating the ability to meet specific requirements for distribution and use imposed either by the manufacturer or the FDA.

Four general categories or causes of shortages:

1. Manufacturing Problems
 - Slowdowns/shutdowns
 - cGMP
 - raw materials difficulties
 - ramp-up during approval/small lot size, short shelf life
 - timing
2. Economics
 - Going out of business
 - Economic incentive to produce (too much liability, not enough profitability)
3. Demand forecasting
 - Forward buying
 - Just-in-time inventory
 - Regional shortages
 - DEA quotas
 - Additional uses/unforeseen market growth
4. Unique Risk
 - Potential for mortal or serious injury
 - Potential for injury to unintended recipients

(HDMA Drug Shortages Issue Paper, Spring 2001)

- According to the American Enterprise Institute, vaccines account for less than 2% of the pharmaceutical market or less than 0.2% of total U.S. health costs. The \$400 - \$600 cost of the recommended round of childhood vaccines is spread out over 16 years, with the truly needy qualifying for Medicaid or the federally funded State Children’s Health Insurance Program (Wall Street Journal, 8/15/03).

CAUSES

- Thirty years ago, there were 25 vaccine manufacturers in the U.S., today there are 5 (The Washington Times, 12/22/03).
- Sudden demand for product can stretch raw materials. With suppliers in many countries, war, disease, and natural disasters may delay shipping. Degradation and contamination may occur before they even arrive at the manufacturer (Drug Topics, 9/17/02).
- When shortages occur, pharmacists and physicians often make the situation worse by turning to the alternative drug, causing a sudden influx of requests, and another shortage (Drug Topics, 9/17/02).
- Since the majority of injectables are very sensitive, aging facilities affect the quality and viability of product. Upgrading a facility is often expensive and complex, and a manufacturer may find it more fiscally attractive to halt production (Drug Topics, 9/17/02).

GOVERNMENT

- The Bush administration plans to help modernize vaccine manufacturing to avoid delays and shortages. In the January spending bill, Congress is likely to approve \$50 million, half of what is being requested (The Wall Street Journal, 12/17/03).
- HHS estimates that it would cost \$50 million to cover vaccinations for underinsured children at immunization clinics. This program would go into effect immediately if approved (Pediatric News, 3/1/03).
- The president’s fiscal 2004 national budget request for the Vaccines For Children (VFC) program includes \$707 million to create a national stockpile for childhood vaccines as well as \$55 million to fund legislative proposals to improve access to VFC vaccines. The legislation would lift the price caps, allowing the VFC to buy 2.5 million doses in 2004, at a cost of \$5 million (Pediatric News, 3/1/03).
- Under legislation proposed by Sen Landrau, the CDC would recommend how many flu doses are needed, and manufacturers would be reimbursed by the government for any unused doses produced to meet the recommendation (Times-Picayune, 1/29/04).
- The government made a deal with MedImmune to buy nasal flu vaccine doses at \$20 per instead of the usual \$46 per dose (The Washington Post, 12/22/03).
- The Army is considering developing its own pharmaceuticals unit that would manufacture drugs and vaccines for which there is military need but no consumer market (The Asian Wall Street Journal, 1/10/03).

VACCINE SHORTAGES

- The 2003 flu season vaccine was based on a strain that was not as prevalent as first anticipated, with three quarters of patients being affected by the new strain, Fujian. The severity of this strain has driven Americans to get their flu shots, creating a major vaccine shortage (Bangor Daily News, 12/17/03).
- Due to production problems at Wyeth, there is a shortage in Prevnar, a childhood disease vaccine (New York Times, 3/3/04).
- Between late 2000 and the spring of 2003, the U.S. experienced shortages of vaccines against 8 of 11 preventable diseases in children (Medical Letter on the CDC and FDA, 2/8/04).
- Vaccine shortage can also be caused when there is a suddenly increased demand as guidelines for inoculations change (Portland Oregonian, 2/20/03).
- According to a study done by the University of Michigan (funded by the CDC), three-quarters of 405 doctors offices surveyed in 12 states reported problems with consistently getting enough Prevnar, a vaccine given to children to prevent meningitis and pneumonia (Medical Letter on the CDC & FDA, 3/2/03).
- In September 2001, the shortage led the CDC to alter the recommended vaccination schedule to prioritize the vaccine supply to be sure infants got at least 2 of the 4 recommended doses (Medical Letter on the CDC & FDA, 3/2/03).
- Companies have little or no incentive to continue making a vaccine that is not a high earner, especially when costs would have to be incurred to upgrade the manufacturing facilities. Plant upgrades, production increases, and higher shipping costs are all expenses passed on to the consumer (Cincinnati Enquirer, 4/17/02).

ASHP: CURRENT DRUG PRODUCT SHORTAGE BULLETINS

Generic Name	Revision Date
Penicillin G Potassium, Penicillin G Sodium	4/2/2004
Bacitracin	3/30/2004
Methohexital	3/30/2004
Bacitracin	3/30/2004
Methadone Hydrochloride	3/25/2004
Morphine Sulfate	3/25/2004

*Highlighting denotes key facts/statistics.

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Triamcinolone Diacetate	3/23/2004
Betamethasone Acetate And Sodium Phosphate	3/23/2004
Triamcinolone Diacetate	3/23/2004
Atracurium Besylate	3/18/2004
Succinylcholine Chloride	3/18/2004
Hydrocortisone Sodium Succinate	3/17/2004
Hydrocortisone Sodium Succinate	3/17/2004
Methylprednisolone Sodium Succinate	3/17/2004
Hydrocortisone Sodium Succinate	3/17/2004
Erythromycin Lactobionate	3/15/2004
Amphotericin B	3/9/2004
Diphenhydramine Hydrochloride	3/9/2004
Benzotropine Mesylate	3/9/2004
Amphotericin B	3/9/2004
Pneumococcal 7-Valent Conjugate Vaccine	3/3/2004
Amobarbital Sodium	3/2/2004
Gold Sodium Thiomalate	3/2/2004
Ganciclovir	2/25/2004
Valganciclovir	2/25/2004
Antivenin (Crotalidae) Polyvalent	2/25/2004
Crotalidae Polyvalent Immune Fab	2/25/2004
Indomethacin	2/4/2004
Hyaluronidase	2/4/2004
Triamcinolone Hexacetonide	1/16/2004
Pantoprazole Sodium	1/14/2004
Hydromorphone	12/11/2003
Chlorothiazide	11/4/2003
Ethacrynic Acid	11/4/2003
Hydrochlorothiazide	11/4/2003

Source: ASHP, 4/8/04 (<http://www.ashp.org/shortage/index.cfm?cfid=22665306&CFToken=61484775>)

ASHP: RESOLVED DRUG PRODUCT BULLETINS

Drug Name	Last Update
Tetanus Toxoid	4/22/03
Sincalide Injection	5/19/03
Thiamine Hydrochloride for Injection	5/23/03
Emergency-Drug Syringes	6/2/03
Bumetanide Injection	6/25/03
Furosemide Injection	6/25/03
Methylprednisolone Acetate for Injection	7/22/03
Lorazepam Oral Solution	8/11/03
Phenobarbital Injection	8/25/03
Etomidate Injection	9/12/03
Secobarbital Capsules	9/12/03
Cisatracurium Besylate Injection	9/24/03
Mivacurium Injection	9/24/03
Pancuronium Bromide Injection	9/24/03
Vecuronium Bromide Injection	9/24/03

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Meropenem for Injection	9/30/03
Vancomycin Hydrochloride Injection	9/30/03
Vancomycin Hydrochloride Oral Capsules	9/30/03
Metoclopramide Injection	10/14/03
Mumps Virus Vaccine Live	10/27/03
Heparin Sodium for Injection	11/5/03
Morphine Sulfate for Injection	12/8/03
Aminophylline	1/22/04
Piperacillin	1/22/04
Piperacillin/Tazobactam	1/22/04
Theophylline Oral Elixir	1/22/04
Thiopental for Injection	1/23/04
Hepatitis A Vaccine Inactivated	1/26/04
Hepatitis B Vaccine Recombinant and Bivalent	1/26/04
Haemophilus Influenzae Type B Conjugate	
Prochlorperazine	1/26/04
Promethazine	1/26/04
Thioguanine	2/25/04
Ethacrynic Acid	3/3/04
Meperidine Hydrochloride for Injection	3/25/04

Source: ASHP, 4/8/04 (www.ashp.org/shortage/resolved.cfm?cfid=22665306&CFToken=61484775)

FDA:

Current Drug Shortages			
Drug Name	Date	Company Information	Reason for Shortage
Amphotericin B injection	updated 9/29/2003	X-GEN (formerly Pharma-Tek) and Geneva	Manufacturing delays
Cytovene Powder for Injection	updated 1/10/2003	Roche	Previous Production Problems
Duragesic	(Posted 4/6/2004)	Janssen Pharmaceutica Products, L.P.	Manufacturing Issues
Penicillin G Potassium and Penicillin G Sodium Injectables	(Posted 4/6/2004)	Sandoz and Baxter	Supply problems
Solu-Cortef for injection	updated 1/30/2004	Pharmacia	Capacity Constraints
Solu-Medrol for injection	updated 1/30/2004	Pharmacia	Capacity Constraints
TABLOID brand Thioguanine 40 mg Tablets	updated 5/6/2003	GlaxoSmithKline	Manufacturing Issues
Thiola 100 mg tablets	updated 1/17/2003	Mission Pharmacal	Mission and FDA continuing to work to resolve this shortage
Resolved Drug Shortages			
Drug Name	Date	Company Information	Related Information
ALBENZA tablets	updated 3/16/2004	GlaxoSmithKline	Product now available
Amytal for Injection, USP, 0.5 g	2/26/2004	Ranbaxy Pharmaceuticals	Amytal injection is now available.

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Gold Injectables	10/3/2003	SAB-Pharma	In response to the recent shortage, SAB-Pharma has started manufacturing and distributing gold sodium thiomalate injection in 1 mL ampoules.
MERREM I.V.	9/16/2003	AstraZeneca Pharmaceuticals LP	Available through normal distribution.
Phospholine Iodide 0.125% solution	1/13/2004	Wyeth	Now available.
Piperacillin injection	2/4/2004	APP (American Pharmaceutical Partners)	Available from wholesalers as of 1/12/04
Regonol injection	11/10/2003	SAB-Pharma	SAB-Pharma recently acquired this product and reports availability.
Discontinuations			
Drug Name		Company Information	Related Information
Calciferol injection in oil (ergocalciferol)	3/19/2004	Schwarz Pharma	Schwarz has discontinued manufacturing of calciferol
ELAVIL (amitriptyline hydrochloride) Tablets and Injection.	5/15/2003	AstraZeneca Pharmaceuticals LP	No longer available.
Inulin in Sodium Chloride Injection, USP	9/26/2003	Questcor Pharmaceuticals, Inc.	
Kefzol all presentations	2/28/2003	Eli Lilly and Company	
Kefurox all presentations	2/28/2003	Eli Lilly and Company	
Mandol all presentations	2/28/2003	Eli Lilly and Company	
Novolin L, Lente, human insulin zinc suspension [rDNA origin]	7/15/2003	Novo Nordisk Pharmaceuticals, Inc.	
ORLAAM Oral Solution, 10 mg/mL	9/2/2003	Roxane Laboratories	
Serevent Inhalation Aerosol	6/10/2003	GlaxoSmithKline 1-800-340-3236	No longer be available starting in June 2003.
Stelazine	12/18/2003	GlaxoSmithKline	Discontinued and withdrawn from the market.
Suprax	updated 2/25/2004	Lederle/Wyeth Pharmaceuticals	Discontinued July 2002.
TONOCARD tablets	5/29/2003	AstraZeneca LP	Discontinued on December 31, 2003.
Valstar Solution for Intravesical Instillation	1/30/2004	Formerly distributed by Celltech	No further availability planned at this time.
Velosulin BR Human, Buffered Regular Human Insulin Injection [rDNA origin]	11/3/2003	Novo Nordisk Pharmaceuticals, Inc.	-
Wydase	1/30/2004	Wyeth-Ayerst	Discontinued.
Zyflo Filmtab Tablets	7/9/2003	Abbott Laboratories	Discontinued June 2003.

Source: CDER, 4/9/04 (www.fda.gov/cder/drug/shortages)

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