

SPECIAL SUPPLY CHAIN REPORT

The Life Sciences Industry

Created by Resilinc Risk Analysis Team
Updated: November 18, 2022



Executive Summary

This special report will cover impacts to the Life Science industry including drug shortages, medical device recalls, production slowdowns, and more. Shortages of drugs and medical devices across the world are impacting hospitals, pharmacies, and patients. Disruptions are due to increases in demand, adverse impacts of Covid-19 lockdowns, the Russia-Ukraine war, raw material shortages, and labor and manufacturing disruptions.

Key Takeaways:

- Raw material costs have increased 50-160% in Europe
- Shortages of amoxicillin and Adderall prevalent in the US
- Overall slower YoY growth in the medical device industry
- Helium shortage 4.0 is expected to impact future MRI use

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EventWatch^{AI} Notifications

Impacts to: Biotechnology, Healthcare, Human Health, Life Sciences, Pharmaceutical

Date	Event Type	Event
11/18/22	Factory Disruption	Packaging Corporation of America to Idle its Mill in Jackson, Alabama, USA
11/18/22	Legal Action	Johnson & Johnson Faces Class Action Lawsuit in UK over Asbestos Contamination in its Talc Products
11/18/22	Cyber Attack	CorrectCare Integrated Health Hit by a Cyber Attack
11/17/22	Leadership Transition	Intermountain Healthcare Appoints New CEO
11/17/22	Merger & Acquisition	Avenga Acquires IncludIT
11/17/22	Merger & Acquisition	Mesa Laboratories Acquires Peptide Purification Business from Belyntic
11/17/22	Cyber Attack	Lake Charles Memorial Health (LCMH) Suffers Cyber Attack
11/16/22	Leadership Transition	Xerox Appoints New COO
11/16/22	Fine	Takeda to Settle Investment Claims
11/16/22	Business Sale	Update: LogicBio Completes its Sale to Alexion, AstraZeneca Rare Disease
11/16/22	Labor Disruption	Thermo Fisher Scientific Lays Off Workers in Grand Island, New York, USA
11/15/22	Fine	Walmart Announces Nationwide Opioid Settlement in the USA
11/15/22	Factory Fire	Explosion at Vision Drug Factory in West Godavari, Andhra Pradesh, India
11/14/22	Merger & Acquisition	Zekelan Industries to Acquire Assets from SPS Companies
11/14/22	Corporate Restructuring	Illumina to Trim its Workforce
11/14/22	Business Sale	Novartis to Sell One of Its Manufacturing Facility in Singapore to BioNTech

Drug Shortages

Last Updated: 11/15/22



Drug Shortages in the US: Amoxicillin

Background: Amoxicillin Shortage

- Used to treat specific infections caused by growing bacteria such as pneumonia, bronchitis, and infections of the ears, nose, throat, urinary tract, and skin – commonly used to treat children

Causes

- Increase in demand

Current Situation

- **The FDA has reported the liquid version/oral solution of amoxicillin in shortage**
 - **No timeline for when the drug will be fully back in stock**
- Companies allocating supplies for current existing customers
- **Other antibiotics can be used in place of amoxicillin**
 - Considered a “first-line” therapy according to the CDC
- Greater impacts to hospitals > pharmacies
 - Regionalized shortages reported at specific CVS stores (The Hill)

Producers Facing Shortages

- Hikma Pharmaceuticals, Teva, and Sandoz (American Society of Health System Pharmacists (AHSP))
 - **Hikma has reported having adequate supplies to meet their agreed upon commitments with current customers**

Drug Shortages in the US: Adderall

Background: Adderall Shortage

- Drug shortage warning for Adderall, amphetamine mixed salts, due to manufacturing delays by Teva (FDA)
- **64% of 360 independent pharmacies reported difficulty obtaining Adderall** (National Community Pharmacists Association (NCPA))
 - **Nearly two-thirds of community drugstores in the USA reported problems ordering Adderall in July and August**

Causes

- Increases in demand, manufacturing disruptions, and labor shortages on Teva's packaging line
 - **Unable to meet demand** due to manufacturing limits by the federal government - **Supply from other manufacturers not efficient to meet US demand**

Current Situation

- **Teva is likely to face challenges for the next two to three months**
 - **Estimated dates for recovery of supply ranges from October 2022 to March 2023** – depends on dosage and form
- No readily available drug that can be used as an alternate agent

Producers Facing Shortages

- Teva, Amneal Pharmaceuticals, Rhodes Pharmaceuticals, Sandoz - **sell over half of all generic extended-release Adderall in the US**
 - Teva is the largest supplier of branded and generic versions of Adderall

Recent Drug Shortages in the US

Recent Drug Shortages Announced by FDA	Companies Announcing Shortage	Cause	Recovery Time
Alprostadil	Mylan	Unspecified reasons	No estimation
Verteporfin	Bausch & Lomb	Manufacturing & shipping delays	End of December 2022
Potassium Chloride	B. Braun Medical Inc.	Unspecified reasons - Backorder	Undisclosed
Amphetamine Salts	Epic Pharma	Unspecified reasons	No estimation
Amphetamine Salts	Rhodes Pharmaceuticals L.P.	Unavailability of active ingredients	No estimation
Amphetamine Salts	SpecGX LLC	Unspecified reasons	No estimation – supply chain constraints until January 2023
Amphetamine Salts	Teva Pharmaceuticals	Unspecified reasons	October 2022-December 2022
Atropine Sulfate	Hospira, Inc.	Increase in demand	Next stock: November 2022; Estimated recovery: June 2023
Bacteriostatic 0.9% Sodium Chloride	Fresenius Kabi USA, LLC	Increase in demand	Next product release: November 2022
Bacteriostatic 0.9% Sodium Chloride	Hospira, Inc.	Increase in demand	Next delivery: March 2023; Estimated recovery: June 2023
Bacteriostatic Water	Hospira, Inc.	Unspecified reasons	Estimated recovery: June 2023
Bumetanide	Hikma Pharmaceuticals USA, Inc.	Increase in demand	Undisclosed
Bupivacaine Hydrochloride and Epinephrine Injection	Hospira, Inc.	Unspecified reasons	Estimated recovery: December 2023

Drug Shortages in Europe

- Aside from the US, Europe is also facing extreme drug shortages due to impacts of Covid-19, the Russia-Ukraine war, and soaring energy costs
- In Europe, generic drug manufacturers have warned of reduced production due to energy costs
- **Electricity prices have risen tenfold for some drug manufacturing plants in Europe**
 - **Raw material costs have risen by 50-160%**
- **Generics account for roughly 70% of all dispensed medicines in Europe** (Medicines for Europe)
 - Many of them are used to treat serious conditions such as infections and cancer, but make up only 29% of the region's drug bills
- The Medicines for Europe group issued a letter to the EU member states' energy and health ministers warning that its representative companies may stop manufacturing some cheap generic drugs
 - The association is looking for an exemption for the pharmaceutical industry from the EU's directives aimed at reducing energy consumption
 - The association in EU member states are also petitioning national health authorities for more flexibility on drug prices
- The group has warned that **some of its producers are at risk of having gas supplies rationed or not being able to continue manufacturing activities**
 - Companies potentially affected: Teva Pharmaceutical Industries; Sandoz; Fresenius Kabi; Centrient Pharmaceuticals; Bluefish Pharmaceuticals; Medichem S.A.

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Causes

- Impacts of Covid-19, the Russia-Ukraine war, and soaring energy costs

Current Situation

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Producers Impacted

- Teva Pharmaceutical Industries; Sandoz; Fresenius Kabi; Centrient Pharmaceuticals; Bluefish Pharmaceuticals; Medichem S.A.

Drug Shortages in China

- Previous shortages of iodinated contrast media are still impacting the healthcare industry today
- Shortages due to a previous shutdown of the GE Healthcare production facility for iodinated contrast media in Shanghai, China
 - The plant is now open and running at full capacity
- Causing a current shortage of iodixanol injections

Products Affected	Company	Type	Recovery
Visipaque solution for injection	GE Healthcare	270mg/mL, 50mL +PLUSPAK bottle, 10 count, NDC 00407-2222-16	Q1 2023
Visipaque solution for injection	GE Healthcare	320mg/mL, 150mL +PLUSPAK bottle, 10 count, NDC 00407-2223-19	Q1 2023
Visipaque solution for injection	GE Healthcare	320 mg/mL, 500mL +PLUSPAK bottle, 10 count, NDC 00407-2223-23	Q1 2023

Medical Devices

Last Updated: 11/18/22



Impacts to the Medical Device Industry

- Medical device producers are struggling to produce parts for devices due to inflation, increasing demand, and global supply chain disruptions
 - The amount of procedures across hospitals has risen
- Companies are raising prices to combat the impact of **inflation on material costs for electronic components**
 - Stryker Corp., has raised prices and slowed purchases and production in order to find better prices. The company makes surgical equipment and joint-replacement parts
 - Abbot Laboratories is struggling to meet demand for older models of Libre blood-sugar monitoring devices (WSJ). Due to **shortages of older semiconductors**. The company expects **constraints to ease over the next couple of months**
- Electronic parts like semiconductors are not the only shortage companies are facing in device making
 - **Shortages of specialized plastics, metals, and resins**
- These shortages will result in slower YoY growth for the industry for a 7.8% increase in 2022 to \$498.7Bn globally
 - Last year, the medical device industry grew 8.1% (Frost & Sullivan)
 - Shortages of nurses and technicians is also contributing to slower growth – Edwards Lifesciences Corp. reported nurse shortages as a reason for its Q3 sales to rise only 1% YoY (WSJ)

Helium Shortages

Background on Helium

- Produced as a byproduct of natural gas refinement at 14 plants around the world
- This is the fourth worldwide shortage of helium since 2006 – the industry has dubbed it “Helium Shortage 4.0”

Causes & Contributors

- Multiple impacts to supplies at different plants over the last two years
- Fire and explosion at Amur plant in eastern Russia – delayed timeline for the new facility **meant to supply roughly one-third of the world’s helium**
 - The plant faced a fire on October 8th, 2021 and an explosion on January 5th, 2022
- January 2022 leak at Cliffside, Texas plant – shut down for emergency repairs for four months
 - Plant went up for auction in the summer
 - **Loss of one-third global helium supply**

Current Situation

- Four of five major US suppliers are rationing the element
- Costs have risen roughly 30%. The current price is \$3.89 per HNT with a 24-hour trading volume of \$5,124,974 as of November 7th

Helium Shortages

Applications/Benefits of Helium

- Helium has a few applications in the healthcare, biopharma, and life sciences industries
- Helium mixes for ailments that restrict airflow to lungs: asthma, chronic pulmonary disease, etc.
- Medical research for MRIs and nuclear magnetic resonance spectroscopies (NMR)
 - Those using helium in medical research have been impacted by the shortage
- Keeping organs cool during transplants

Helium and MRI Machines

- Magnets in MRI machines require liquid helium in order to operate
 - Over the lifetime of an MRI machine, 10,000L of helium is needed – 2,000L at a time
- **As of now, MRIs for patients have not yet been postponed and machines have not been shut down by hospitals**
 - Suppliers are giving the healthcare industry priority for helium by cutting back on allocations to less important clients
- To combat the impacts of a shortage, medical equipment manufacturers such as GE Healthcare and Siemens Healthineers are attempting to develop MRIs that require less liquid helium
 - Researchers have also looked into helium free MRI machines

Recent Medical Device Recalls

- Medical device recalls were issued for Shanghai United Imaging Healthcare and Medline Industries on October 13th by the FDA
- Shanghai United Imaging Healthcare issued a class 2 device recall on Positron Emission Tomography and Computed Tomography System
 - Recall due to ECG signal and respiratory signal loss due to Wi-Fi interference
 - Signal loss during acquisition can result in the failure of ECG and respiratory-gated reconstruction of the PET scan
- Medline Industries issued a class 2 device recall on VENCLOSE, VENCLOSE PROCEDURE PACK, 7VM, REF VC-PPH-67A, cardiovascular procedure convenience kit
 - Recall due to incorrect sizing of introducer/sheath component
- The FDA also announced recalls for Siemens Medical - a class 2 recall was announced on ARTIS pheno due to potential software issues
 - Could lead to a hazardous situation for patients if treatment cannot be continued on the system
- Encore Medical issued a class 2 recall on EMPOWER 3D Knee Tibial Insertas due to a mix up of products in the wrong boxes
 - Could lead to implants not being available for surgeries, which would cause delays in surgery

EventWatch^{AI} Notifications on Medical Device Recalls

Date	Event
11/18/22	Medical Device Recalls for Tollos, Medtronic Navigation, and Novapproach Spine
11/18/22	MHRA Issued Nationwide Recall for Martindale Pharma in the UK
11/17/22	Medical Device Recalls for Texas Medical Technology, Steris Corporation, and Altimate Medical
11/17/22	Japan PMDA Issued Nationwide Recall for Medtronic, Johnson & Johnson K.K., Fujifilm Corporation, Cosmo Tech, D-Tech, and PGV
11/16/22	Health Canada Issues Nationwide Recall for Southmedic and ALK-Abello Pharmaceuticals
11/15/22	Medical Device Recalls for Getinge, Howmedica Osteonics, Atrium Medical Corporation, and Insulet Corporation
11/15/22	Medical Device Recalls for Baxter Healthcare Corporation, Becton Dickinson
11/13/22	Medical Device Recalls for Canadian Hospital Specialties, DeVilbiss Healthcare, Carefusion 2200, Boston Scientific, Covidien, Spectranetics Corporation, LeMaitre Vascular
11/11/22	Medical Device Recalls for Ortho-Clinical Diagnostics, CooperSurgical, and X-NAV Technologies
11/8/22	Medical Device Recalls for Access Vascular, Beaver Visitec, Avanos Medical, Alphatec Spine, Medtronic MiniMed, and Canon Medical System
11/5/22	Medical Device Recalls for SEDECAL SA, Fresenius Medical Care, IRhythm Technologies, and Ferno-Washington
11/4/22	Teleflex Issues Class I Recall for its Respiratory Filters

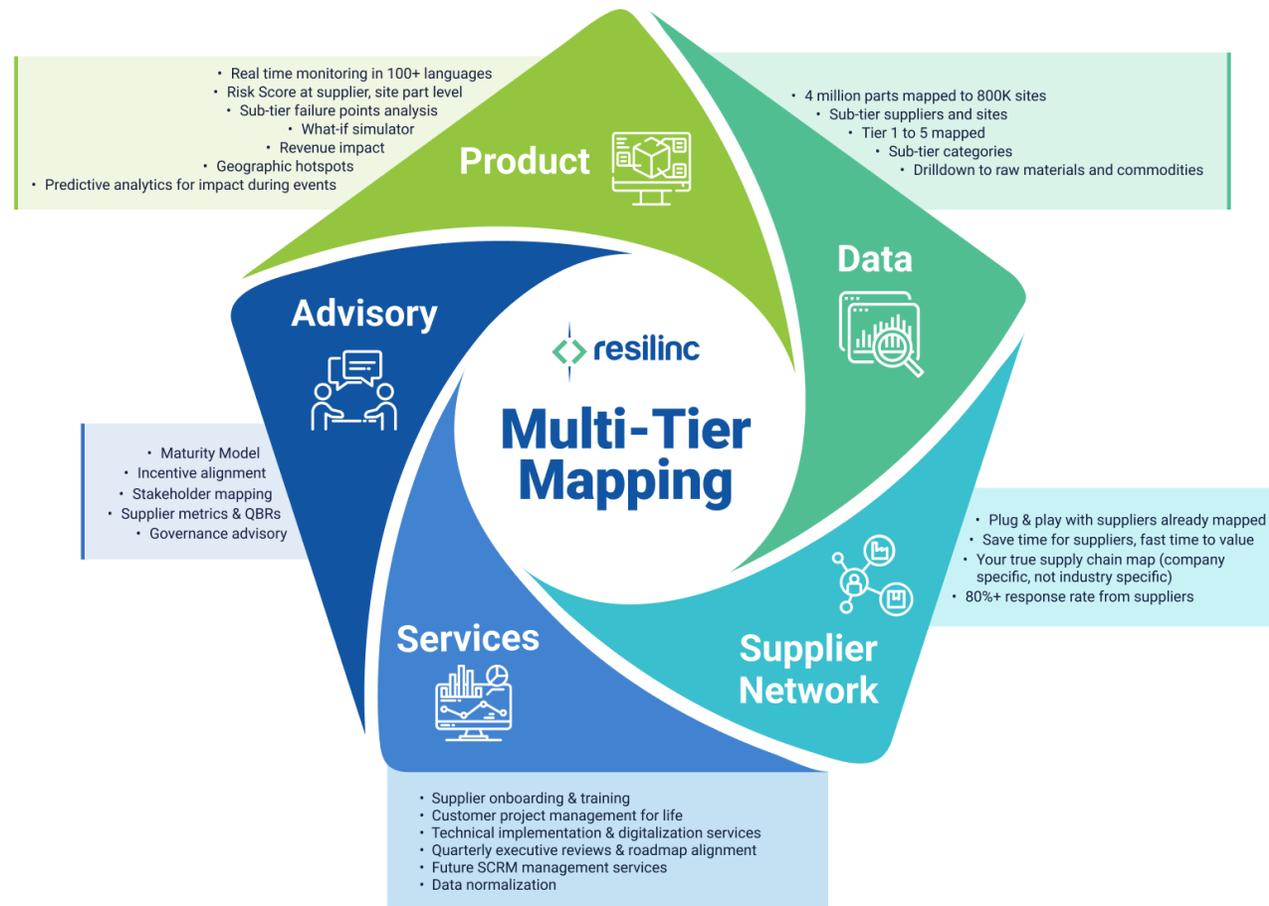
Outlook & Resilinc Solutions

Last Updated: 11/15/22



Outlook on Healthcare and Life Science Industries

- Shortages will continue into 2023 due to high energy costs, labor shortages, manufacturing disruptions, and an increase in filled beds at hospitals causing higher demand for drugs and machines
- Impacts to European generic drug manufacturers
 - Map your suppliers to see if you have any sites in Europe that will be impacted by production cuts due to high energy costs
 - As the energy crisis gets better after winter months, drug production may ramp up again
- Find alternate sites for those that are facing production cuts, shortages, or recalls
 - Companies will continue to cut production of drugs that do not create revenue due to higher production costs
- Collaborate with suppliers to create long-term contracts for drugs or devices to ensure you will not be impacted by a shortage
- Increased innovation in Chinese healthcare sector due to increasing age of residents



6-12 Month Outlook on Global Supply Chain

- Labor strikes to continue in the US and Europe due to inflation caused by the Russia-Ukraine war which resulted in an energy crisis in Europe
 - Employees demanding higher pay to compensate for inflation. Also asking for better working conditions: sick days off, bereavement, etc.
 - Labor shortages impacting transportation and manufacturing
- High energy costs to impact most industries in the supply chain
 - Energy intensive industries like steel, aluminum, and fertilizer are greatly impacted in Europe
- Shipping costs to increase if energy supplies get smaller and energy costs rise
 - Current US diesel shortage – short term shortage that should be resolved before the end of the year
 - Energy production impacted across France – lack of gas at petrol stations
- Increasing amount of cyberattacks - ensure your supply chain is safe from possible cyber attacks
 - Cyber attacks can also impact Internet of Things (IoT). IoT devices employ sensors to detect their position, temperature, humidity, light levels, movement, handling, and speed
 - Cyberattacks on IoTs can harm products that are sensitive to light or temperature. Impacted products can result in revenue loss and recalls
- **Inflation to continue rising into 2023** – raw material costs to increase with higher inflation
 - The Congressional Budget Office expects the **consumer price index to rise 3.1% in 2023** – still above the long-term baseline of 2.3%



Thank You!

Got feedback? We want to hear it at
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