AHRMM
Advancing Health Care through
Supply Chain Excellence

American Hospital Association™
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Supply Chain Resource Council (SCRC) Report

February 13, 2023 Meeting

Executive Summary

Supply shortages as a percent of overall orders placed is trending downward with business processes and procedures implemented by healthcare organizations recognized as contributing factors to these improved conditions. That said, order fill-rates continue to hover in 20-25% range and vary by product category, and a familiar list of supply shortages continue to cause concern for supply chain professionals.

Mexico's new GMP regulation, challenges with single-use tourniquet cuffs, the U.S. Geological Survey (USGS) solicitation of comments regarding the Helium supply risk and information on charities and earthquake related donations and aid to Turkey and Syria round out the conversations from this week's supply chain leaders which can be found in the full Council report below.

▲ Discussion: New Guidelines For Good Manufacturing Practices Concerning Medical Devices In Mexico

There is a new regulation that will go into effect in Mexico on June 23, 2023 which will mandate additional inspections within their export only zones – zones that allow for easy movement of products between the Mexico and its global trading partners. The regulation is calling for additional GMP inspections on export products that are FDA and ISO compliant. Concerns are centered on the redundancy of these inspections, the current backlog of regulatory approvals and the additional strain this could place on the limited number of existing staff and resources leading to the delay of product exports.

There is a large number of product manufacturers, sterilization and labeling/packaging facilities that will be impacted by this regulation. AdvaMed has briefed U.S. Trade Representatives, Commerce Department, FDA and the White House.

▲ Disaster relief Donations for Turkey and Syria

- **Attached** is a list of urgent medicine and medical supplies from the Health Attaché of the Turkish Embassy in DC. The Embassy has stopped accepting PPE and Disinfectant products as they have sufficient supplies.
- People are able to assist by sending items by mail or through in-person drop off to the Turkish Embassy and Turkish Consulates across the U.S. Click here to view Turkish Embassy and Consulate locations.
- Charity Navigator and Charity Watch are two organizations that have vetted several charities. Click these links to view those charities.

▲ Supply Chain Watch List – supply shortages causing concern in the field

- Product availability challenges have resurfaced with single-use, non-sterile blood pressure cuffs. This was first reported in the October 24th SCRC report. Recent information from Stryker and a GPO has indicated the shortage is projected to last through 2023. While health care organizations are hesitant to sanitize the single-use cuffs, some are exploring cleaning processes in an effort to avoid the negative impact to patient care, procedures and trauma cases. Attached is one organization's cleaning process.
- Tyvek shortages and the re-sterilization process (of a non-sterile use product) by the OEM are compounding product availability.
- Supply shortages as a percent of overall orders placed is trending downward from the peak levels seen in the past, however they are not as low as pre-pandemic levels. Business processes and procedures implemented by healthcare organizations are recognized as contributing factors to these improved conditions.

- Fill-rates from key trading partners remain low with some health care organizations reporting 20-25% "on-time and full" and "first fill by promise date" fulfillment levels. Fill percentages vary by product category.
- Recurring themes driving the supply shortages include, raw materials, increased demand, lack of sterilization capacity, logistics and medical grade paper for sealing products. The compulsory move to direct orders vs. distribution is another factor leading to the varied fill-rates as well as adding to existing operational workloads.
- Other items of concern that were shared by hospitals leaders and ECRI's member survey:
    - Staplers and sutures
    - 3M SteriDrapes and Ioban
    - 3M Electrodes
    - Zoll Batteries
    - Disposable Inner Cannulas
    - Medtronic Shiley Trachs
    - BD Scalp Monitors
    - Stryker Bone Cement mixing accessories

▲ Updates

- **Federal Register:** Request for Comments on Helium Supply Risk
  In light of recent geopolitical events and concurrent with the return of primary helium data-collection responsibility from the Bureau of Land Management (BLM) to the U.S. Geological Survey (USGS), the USGS is soliciting input from the public, including domestic helium users, that will aid the USGS in analyzing whether there is an increasing risk of helium-supply disruption; whether that risk stems from supply from countries that may be unwilling or unable to continue to supply the United States; and whether those risks pose a significant likelihood of increasing the Nation's import reliance or creating a concentration and risk of permanent or intermittent supply disruptions from a small number of international or domestic supply sources.

  You may submit written comments online at http://www.regulations.gov by entering "DOI-2022-0012" in the Search bar and clicking "Search," or by mail to Request for comments on Helium Supply Risk, MS-102, U.S. Geological Survey, 12201 Sunrise Valley Dr, Reston, VA 20192
- Premier has shared the following Helium statistics and data:
    - **Private Industry Cost:** Appears to have gone up nearly 50% in the past year alone. Was relatively stable up to that point.
        - **2022**: The estimated price for private industry's Grade-A helium was about **$11 per cubic meter** ($310 per thousand cubic feet) in 2022, with some producers posting surcharges to this price.
        - 2016-2021: Pricing was about **$7.50 per cubic meter** each year
    - **Import Sources (2018–21)**: Qatar, 53%; Canada, 20%; Algeria, 15%; Russia, 5%; and other, 7%.
        - Last year was the first report year we had Russia listed out
        - In 2013-2016, it was 95% Qatar. 2016: 100% Qatar
            - Prior to 2013, the reports state that the U.S never imported any Helium
        - According to an ad, Canada's largest helium purification facility (NA Helium) is expanding and is expected to double production in 2023

- **Helium Applications:** In 2022, estimated domestic apparent consumption of Grade-A helium was 43 million cubic meters (1.5 billion cubic feet)
    - The 2019 Report below provides specific percentages by application:

Application (2019 Report)	Percent
Magnetic resonance imaging	30%
Lifting gas	17%
Analytical and laboratory applications	14%
Welding	9%
Engineering and scientific applications	6%
Leak detection	5%
Semiconductor manufacturing	5%
Various other minor applications	14%

    - With the various domestic semiconductor manufacturing initiatives planned, we would assume the that specific percent would rise in the future

- **World Resources:** Helium resources of the world, exclusive of the United States, were estimated to be about **31.3 billion** cubic meters (1.13 trillion cubic feet).
    - The locations and volumes of the major deposits, in billion cubic meters, are:
        - Qatar, 10.1; Algeria, 8.2; Russia, 6.8; Canada, 2.0; and China, 1.1.
        - The US has 60.7 billion cubic meters in the Federal helium inventory

- **Expiration of the Public Health Emergency and impact to Emergency Use Authorizations**

  AHA recently sent a letter to HHS Secretary Becerra (attached) urging the agency to build on the lessons learned and care delivery advancements made during the PHE and urged the Administration to retain flexibilities that are necessary for continued recovery from the pandemic and to make permanent those that have been essential for more effective, patient-centered care delivery.

  We are also reaching out to the FDA to better understand any impact or corresponding requirements related to Emergency Use Authorizations (EUA's) when the PHE expires, as indicated, on May 11, 2023. Our initial assessment is this should not pose a significant impact to sourcing or on-hand inventory levels; hospitals for the most part have transitioned back to traditional sourcing channels and on-hand inventory levels of PPE continue to remain high.

- **DSCSA Awareness**

  AHRMM is conducting a brief survey to better understand the level of Drug Supply Chain Security Act (DSCSA) preparedness across the health care supply chain. Please take 1 minute to complete the following three-question survey or forward this to the appropriate staff member within your organization.

  The Federal DSCSA places extensive pharmaceutical supply chain security requirements on hospitals and pharmacies. Among those requirements is the obligation to receive and store specific electronic transaction data unique to every individual package of prescription pharmaceuticals purchased.

About the Supply Chain Resource Council (SCRC)

The Supply Chain Resource Council (SCRC) is comprised of over 80 supply chain and health care leaders from across the health care field with the goal of understanding the extent and impact supply shortages and disruptions are having within the hospital and patient care settings, as well as a capturing and documenting solutions to these challenges. Information collected during these calls is drafted into a report and shared with AHA, AHRMM and Professional Management Group (PMG) leaders, the White House Response Team, various Federal Agencies and the broader health care field. *The content of this report represents information, strategies and solutions from SCRC members but does not necessarily reflect policy positions of the AHA.*