SUPPLY CHAIN RESOURCE COUNCIL

AHRMM Advancing Health Care through Supply Chain Excellence

Supply Chain Resource Council (SCRC) Report

November 11, 2024

Executive Summary

Primary topics discussed this month were the Baxter IV Fluid shortage and the BD BACTEC™ situation. Raw material constraints impacting availability of Baxter/Welch Allyn blood pressure cuffs and several situations currently being monitored round out our report for this month.

Details can be found in the full report below, and on the Supply Chain Resource Council webpage.

▲ Field Updates

- As previously projected, **Baxter restarted a second IV solutions manufacturing line this week.** Together with the line restarted the week of Oct. 28, these two lines represent – at their peak operation (prior to Hurricane Helene) – approximately 50% of the site's total production and approximately 85% of the site's production of one-liter IV solutions, the most commonly used size by hospitals and clinics.
    - SCRC members stated that they are not seeing any relief. Effective communication regarding allocation fulfillment timeframes was urged.
    - Increasing patient volumes are placing an additional strain upon existing allocation levels.
    - Baxter shared an Anticipated Allocation Changes notice on November 11th based on its expectation for increased production of IV fluids. *The allocation letter is attached to this email.*

BD is shifting production of BD BACTEC™ Lytic Anaerobic Media in plastic (442021) more heavily to glass bottles (442265). As a result, BD states customers will experience a tightening of Lytic Media in plastic bottles however, Lytic Media in glass is readily available for purchase. BD BACTEC™ Bottle Holders are available to support glass vial adoption. *More information can be found in the attached Dear Valued Customer letter.*

The message in the letter aligns with a video update from Chris Beddard, VP Global Platform Leader, Microbiology at BD, and Ana Maria, Senior Director Global Medical Affairs at BD was posted to their BACTEC website earlier this week: https://bdbactec-update.com/#.

All BD BACTEC™ SKUs, with the exception of plastic lytic anaerobic, have strong DIOH. For lytic anaerobic, a switch to GLASS lytic is available for all customers to support clinical care.

- Some SCRC members have experienced failed validation sequences for the glass bottles while others have begun using the glass bottles.
- Concerns over meeting CMS Quality Metrics were expressed.
- ThermoFisher™ Signal Blood Culture one bottle system (BC0100M) is being evaluated as a temporary solution.

Post-meeting update: Baxter/Welch Allyn has announced they have resumed manufacturing and have begun shipping product. Effective Nov. 11 Baxter/Welch Allyn has increased supply allocation of their blood pressure cuffs to 40%. Rolling backorders will continue, and recovery will vary by product. All shifts are running at full capacity until recovery is complete.

In October, Baxter/Welch Allyn announced that they were experiencing a temporary constraint on raw material availability for their blood pressure cuff production out of their manufacturing plant

in Mexico. This unplanned downtime will result in extended lead times, necessitating thoughtful conservation of supply, and implementation of a cleaning protocol to reuse BP cuffs as necessary. Cleaning instructions are available in the Directions For Use (DFU).

According to ECRI, Baxter/Welch Allyn has approximately a 7% market share in the *reusable BP cuff category* for the products affected by the raw materials constraints. For broader context, Baxter/Welch Allyn has approximately 17% overall market share in this product category.

▲ Supply Chain Watch List – Current situations under observation

- **Normas Oficiales Mexicanas (NOM) 241-SSA1-2021 is an integral component of the comprehensive legal framework governing medical devices in Mexico**, playing a pivotal role in guaranteeing the safety, effectiveness, and quality of these products. The most recent iteration of the Mexican Official Standard, NOM-241-SSA1-2021, which addresses Good Manufacturing Practices for Medical Devices (referred to as NOM-241 hereafter), was officially released on December 20, 2021, and became enforceable on June 20, 2023. This updated regulation aligns with international standards and best practices for medical devices.

  It's imperative that each manufacturing site where a medical device is produced possesses a valid GMP certification. This requirement remains consistent across all medical devices, regardless of their risk classification, the scale of the manufacturing facility, or the specific product. NOM-241 provides detailed guidance on meeting COFEPRIS' expectations pertaining to the organization of the establishment, personnel requirements, documentation, facility standards, production control, equipment usage, procedures for product recalls, validation processes, audit protocols, and various other prerequisites essential for compliance.

- **Dupont has filed a complaint with the International Trade Commission** against Xiamen Dangsheng New Materials and affiliates, and Jiangsu Qingyun New Materials and affiliates, among others, to block importation of products that infringe DuPont intellectual property (IP) related to its Tyvek® brand and products. More information can be found in the DuPont Press Release.

- **The BIOSECURE Act** prohibits the US government from entering a contract with any entity, regardless of whether it is a US or foreign company, that (a) uses biotechnology equipment or services provided by a biotechnology company of concern or (b) has entered a contract that uses such equipment or services with a biotechnology company of concern. The BIOSECURE Act defines a "biotechnology company of concern" as an entity that is subject to control or operates on behalf of a US foreign adversary (such as China, Russia, North Korea and Iran), is involved in the biotechnology equipment or service industry and carries out research or services with a foreign adversary's military, internal security or intelligence agencies.

About the Supply Chain Resource Council (SCRC)

The Supply Chain Resource Council (SCRC) is comprised of over 90 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) senior 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.*

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