FOR IMMEDIATE RELEASE

BAXTER REINFORCES GUIDANCE REGARDING URGENT MEDICAL DEVICE CORRECTION FOR EXACTAMIX PRO DUE TO SOFTWARE OVERFILL ERROR

DEERFIELD, Ill., FEBRUARY 27, 2024 – Baxter International Inc. is reinforcing guidance regarding an Urgent Medical Device Correction for **ExactaMix Pro** 1200 and **ExactaMix Pro** 2400 compounders using software versions 2.0.8 and 2.1.8. Baxter notified impacted customers initially in December 2023 and again in February 2024. The Correction is due to an error in the "Use Some Overfill" feature, which may lead to over-delivery of an ingredient into the final admixture. Baxter expects to release a software upgrade to resolve the issue in March 2024. There have been no reports of injury associated with this issue.

ExactaMix Pro 1200 and **ExactaMix Pro** 2400 are automated compounding systems used in pharmacy practice. Compounding refers to the process of combining or mixing ingredients to create a medication tailored to the needs of the individual patient. The error identified in software versions 2.0.8 and 2.1.8 while using the "Use Some Overfill" feature may lead to over-delivery of an ingredient into the final admixture. This issue can result in redundant ingredient delivery of the requested overfill volume. Unintended over-delivery of an ingredient during compounding into the final admixture may lead to serious adverse health consequences including death or permanent disability.

The Correction applies to a specific subset of **ExactaMix Pro** 1200 (Product Code EXM12DY) and **ExactaMix Pro** 2400 (Product Code EXM24DY) compounders in the United States using software versions 2.0.8 and 2.1.8. While customers may continue to use the **ExactaMix Pro** compounders, it is important to implement safeguards until the software solution is deployed. The following reinforced guidance is provided by Baxter for those customers who continue using the **ExactaMix Pro** compounders:

- When the system indicates that ingredients are depleted, operators should choose to "Swap Container" or "Use a Different Container" and not utilize the "Use Some Overfill" feature until the software solution has been implemented. For additional guidance on these alternatives to using the "Use Some Overfill" feature, refer to the information on Replacing a Source

Container on pages 82-83 in the **ExactaMix Pro** 2400 Operator Manual and pages 83-84 in the **ExactaMix Pro** 1200 Operator Manual.

- If the "Use Some Overfill" feature is inadvertently used, operators must ensure that:
    - The "Use Some Overfill" feature is used only once when an ingredient is depleted.
    - When prompted to enter the volume of overfill to use, enter less than the volume left to run stated in the "Swap Container" window.
    - On the **MixCheck** report, verify that all ingredient deliveries that used overfill volume delivered the expected ingredient volume. To do this, users should make a line-by-line comparison of each ingredient's dispensed and ordered volume and should also ensure that the final total volume for the bag aligns with the expected volume.
    - If you observe redundant ingredient delivery using the overfill volume per the **MixCheck** report, discard the bag.
- Always review the final **MixCheck** report as described in the **ExactaMix Pro** Operator Manual. Please review the information on this feature on pages 167-171 in the **ExactaMix Pro** 2400 Operator Manual and pages 164-168 in the **ExactaMix Pro** 1200 Operator Manual.

Customers with additional questions can contact their Baxter sales representative, or Baxter Global Technical Services at 800-678-2292 Monday through Friday between 8 a.m. and 7 p.m. Eastern Time. Any adverse events experienced with the use of this product may be reported using one of the following options:

- Contact Baxter Product Surveillance by navigating to the Baxter Product Feedback Portal at http://productfeedback.baxter.com or email corporate_product_complaints_round_lake@baxter.com.
- Report to the FDA MedWatch Adverse Event Reporting Program:
    - Online: By completing and submitting the report online at https://www.accessdata.fda.gov/scripts/medwatch/.
    - Regular mail or Fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a

reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

Baxter is voluntarily issuing this communication with the knowledge of the U.S. Food and Drug Administration.

About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For more than 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on X/Twitter, LinkedIn and Facebook.

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