



September 2026

UPDATE: TICE® BCG (BCG LIVE for intravesical use)

Dear AUA:

I am writing on behalf of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., to provide you with an update regarding TICE® BCG (BCG LIVE for intravesical use; “TICE BCG”).

Background:

Since 2012, Merck has been the sole US manufacturer and primary global supplier of TICE BCG. Increasing global demand for TICE BCG has exceeded our manufacturing capabilities. In 2021, we announced our decision to build a new manufacturing facility and commit to the reliable and sustainable production of TICE BCG to fulfill demand.

As our company works to complete this facility, we would like to acknowledge the challenges you may have experienced when the supply of TICE BCG has been insufficient to meet market needs. We are sincerely grateful for the patience and efforts of the healthcare practitioners, like you, who navigated the supply limitations for their patients. We share your goal of ensuring that patients have access to the medicines they need.

Update on manufacturing for TICE BCG:

We previously communicated that, barring unforeseen circumstances, our new plant was on track to open by the end of this year. Since then, we’ve encountered a series of delays due to mechanical interdependencies at our new facility. While work is underway to address these issues, the cumulative additional time will delay full startup, filing, and approval of the facility.

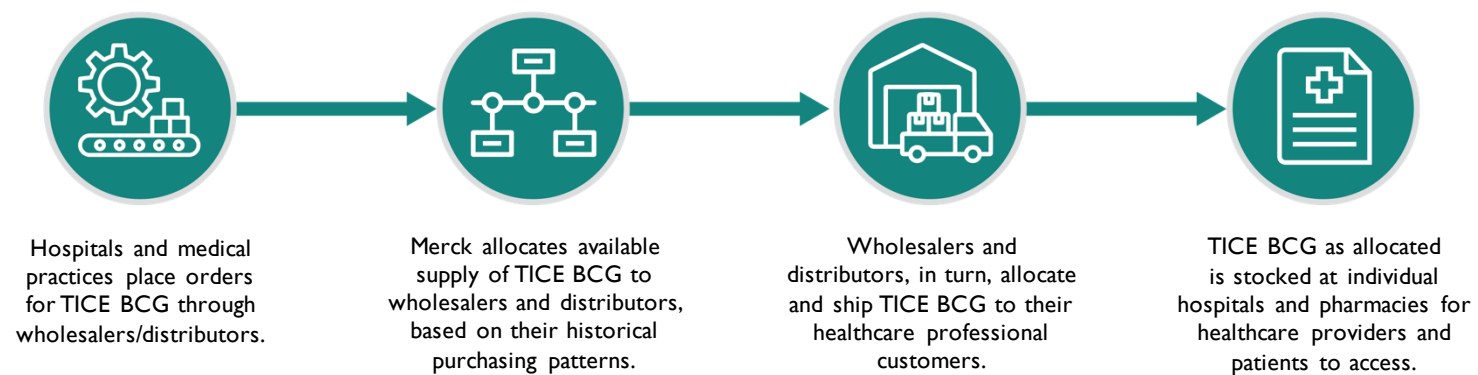
We are working with urgency to address the current challenges and advance the project while taking the necessary steps to reduce the risk of further delays. At this time, we aren’t able to provide an update on timing until all critical testing is completed.

We believe it’s important to remain transparent and keep you informed of developments affecting the facility. We will provide an update on the expected timing of our new facility’s opening in the first quarter of 2027. Once operational, the facility will support a phased ramp-up, with the goal of tripling our TICE BCG manufacturing capacity, which we anticipate will help better meet the needs of physicians and patients over time. In the meantime, we continue to operate the current facility at full capacity.

Supply allocation of TICE BCG:

As a reminder, Merck continues to allocate available supply of TICE BCG to wholesalers and distributors, based on their historical purchasing patterns. In turn, wholesalers and distributors allocate their inventory of TICE BCG to their healthcare professional customers based on available supply and the historical purchasing patterns of those customers. Merck does not directly determine the amount of supply to individual hospitals, hospital pharmacies, or medical practices.

TICE BCG allocation and distribution process:





Merck's commitment:

Supply continuity and sustainability of our medicines and vaccines have been, and remain, two of our highest priorities. We are proud that we have been able to maintain a consistent supply of TICE BCG since 2012, when we became the sole supplier of TICE BCG in the US. The manufacturing of this product is highly complex. Merck continues to do everything we can to complete this new manufacturing project as expediently as possible.

If you have additional questions, you may refer to the TICE BCG frequently asked questions on Merck.com (<https://www.merck.com/stories/addressing-the-global-shortage-of-tice-bcg/>) or contact the Merck National Service Center at 800-NSC-MERCK (800-672-6372).

Regards,

A handwritten signature in black ink, reading 'Jannie Oosthuizen' in a cursive script.

Jannie Oosthuizen
Executive Vice President &
President,
Global Oncology

A handwritten signature in black ink, reading 'John McGrath' in a cursive script.

John McGrath
Senior Vice President,
Global Vaccine Operations