

May 16, 2022

Mr. Greg Eppink
General Manager, GE Healthcare
500 West Monroe St.
Chicago, IL 60661

Re: General Electric Omnipaque Supply Disruption and Product Shortages

Dear Mr. Eppink:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups (including the Association for Health Care Resource & Materials Management (AHRMM)), the American Hospital Association (AHA) is writing regarding the current supply disruptions and shortages of Omnipaque as a result of the temporary closure of GE Healthcare's (GE) manufacturing facility in Shanghai, China. Specifically, we are concerned that the limited availability of Omnipaque products could present significant care delivery challenges for our members, and we ask that GE provide additional information surrounding the current shortage that would be useful in managing care for patients.

America's hospitals, health systems and AHRMM members depend on access to a consistent supply of GE's Omnipaque (iohexol) products to diagnose and treat a broad array of patients, including patients who present in emergency departments, cardiac centers and specialized stroke units with life-threatening or life-altering conditions, where access to contrast media plays a critical role in their diagnosis and treatment. The recent shutdown of the GE production plant in Shanghai due to COVID-19 raises significant concerns about Omnipaque product availability. Those concerns were exacerbated by the fact that the vast majority of Omnipaque products are produced only at GE's Shanghai plant. The shutdown has had direct impact on America's hospitals' and health systems' ability to care for patients and concern remains that prolonged and reduced allocations of Omnipaque will continue to present serious challenges in the future. Moreover, Visipaque, an alternative product for Omnipaque, is currently in backorder, further limiting supply options for our members.



We understand GE has taken several steps to mitigate disruptions while ramping up production of Omnipaque. Specifically, we appreciate GE's quick action to notify its customers and the continued steps it is taking to communicate with all necessary stakeholders. Further, the reopening of the Shanghai plant at 25% capacity in addition to shifting production efforts to a facility in Cork, Ireland, are signs of potential relief for our members and their patients. However, there are several critical issues that require further explanation or clarification so that all involved can navigate the challenges caused by the shortage of Omnipaque. Specifically, it would be immensely helpful if GE could address the following issues:

1. **Allotment Expectations.** Current allotments for Omnipaque products are at 20% with the expectation that those allotment percentages will increase as supply increases. To ensure hospitals and health systems can plan ahead, it would be helpful for GE to provide a clearer set of expectations for how allocations will be managed moving forward, including anticipated projections for increases in allocation based on improvements in GE production and distribution.
2. **Prioritizing Distribution for the Most Critical Services.** Hospitals are already having to prioritize patients and delay many less urgent scans to preserve contrast supplies for the most urgent cases. However, individual hospitals and health systems can only do so much in redistributing the supplies they receive. Efforts to ensure emergent and urgent patients' needs are met can best be assisted if GE also is judiciously allocating its available supplies to those facilities treating the most urgent patients. We believe hospitals that are designated stroke centers, major heart care centers and oncology centers, or those that simply have very active emergency departments should receive special consideration from GE as it chooses how to distribute the product it has available. Can GE provide a clearer set of details pertaining to how prioritization is being done and whether it is considering the patient care services being provided in making those allocation decisions? What steps is GE taking to ensure that patient priority is being factored into distribution systems in a comprehensive, meaningful way?
3. **Distribution Expectations.** We understand and appreciate that GE has moved some production to its plant in Cork, Ireland and has begun sending product to the U.S. by air to speed deliveries. However, considering that the vast majority of Omnipaque is produced in your Shanghai plant, what are GE's plans for distribution of the product manufactured there? In particular, are there plans to expedite shipment via air as GE is doing in Cork?
4. **Extending Current Omnipaque Supply.** While GE's efforts to ramp up production of Omnipaque are encouraging, there will be a period of time in the near future where supply severely fails to meet demand. As a result, providers are doing everything they can to conserve current Omnipaque supply in an effort

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to mitigate disruption. To aid America's hospitals and health systems in these conservation and mitigation efforts, it would be helpful for the GE Medical Affairs team, in coordination with the Food and Drug Administration, to provide national guidance for providers related to extending existing supply through the utilization of sterile compounding practices.

5. **Managing Demand for Rescheduled Services.** Given the severity of this shortage, our members must make decisions about which medical procedures can be delayed to ensure adequate Omnipaque supply for those services that cannot be delayed. The result of this process will be the need to reschedule those delayed services in a timely manner. Once production returns to full capacity, how does GE intend to meet potential increased demand for Omnipaque products to meet supply needs for those rescheduled services?

Thank you again for your communication of critical information to us and our members. In addition, we appreciate your efforts to mitigate production challenges as you work to return to full capacity. Moving forward, we look forward to your response to the issues raised in this letter, and we are committed to partnering with GE to appropriately manage the near-term challenges that lie ahead. Please do not hesitate to contact me if you would like more information or have any questions or concerns.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development