MANCHESTER 1824

The University of Manchester

Vaskar Saha
Professor of Paediatric Oncology

Division of Cancer Sciences
The University of Manchester
Ogilvie Building
Manchester M20 4GJ

Tel (off): 0161 306 0828
Email: v.saha@manchester.ac.uk

April 10th, 2025

Dear EML Secretariat

Re: A.5 Blinatumomab in acute lymphoblastic leukaemia of childhood

As a paediatric oncologist since 1992, I have witnessed and played a small part in the transformative advances in the treatment of childhood Acute Lymphoblastic Leukaemia (ALL). Today, over 90% of children with ALL in high-income countries (HICs) are cured using conventional chemotherapy, augmented by immunotherapies such as Blinatumomab. I was privileged to contribute to the design of the pivotal European study on Blinatumomab in relapsed ALL, which later informed successful trials in the USA for newly diagnosed cases.

However, the disparity between outcomes in HICs and low- and middle-income countries (LMICs)—where over 80% of the world's children reside—is widening. Childhood ALL survival in LMICs lags by 20–30%, and as Blinatumomab becomes standard of care in HICs, this gap threatens to grow further.

The Indian Experience: Building Solutions Locally

Over the past decade, I have focused my efforts at the Tata Medical Center in Kolkata to improve outcomes for children with ALL in India. In 2013, we co-founded the **Indian Childhood Collaborative Leukaemia (ICiCLe) group**, a national research and treatment consortium that now includes over 6,000 systematically treated children.
Key challenges identified through ICiCLe data include:

- **Poor quality of generic drugs**, leading to suboptimal outcomes.
- **Increased toxicity and treatment-related deaths** when using protocols adapted from the West.
- **Financial hardship and treatment abandonment** caused by prolonged, intensive regimens.

The **WHO initiative to ensure high-quality cancer medicines** is a crucial step in addressing the first challenge. Yet, to meaningfully close the survival gap, **access to Blinatumomab**—an effective, well-tolerated immunotherapy—is essential.

Evidence from India: The Impact of Blinatumomab

Through the **Blinatumomab Humanitarian Access Program (BHAP)**, select patients at Tata Medical Center have received the drug since 2020, free of charge. Our findings mirror published data:

- **Excellent tolerance**, with minimal or no toxicity.

- **Molecular remission** in many patients who had poor response to chemotherapy.
- **Long-term remission** without transplant, especially among patients unable to afford allo-HSCT.

Yet, access remains limited—only two other hospitals in India benefit from BHAP. Families across India are now requesting access.

Toward National and Regional Equity

Recognizing the urgent need for equitable cancer care, the **Indian Council of Medical Research (ICMR)** launched a national implementation program in 2024 to deliver ICiCLe-standard care across India. We are also collaborating with neighbouring countries in South Asia and Africa to share the knowledge acquired. **Universal access to Blinatumomab through the WHO Essential Medicines Program** is critical to scaling this progress. Only then can carefully selected children across all partner sites benefit from this life-saving therapy and deliver equity of care.

Call to Action

I respectfully urge global health stakeholders and the WHO to:

1. **Expand access to Blinatumomab** through inclusion in WHO's access programs and procurement channels.
2. **Support national efforts** in India and other LMICs to deliver equitable cancer care based on collaborative treatment models.
3. **Ensure sustainability** through ongoing support, training, and supply chain partnerships for essential cancer medicines.

Every child deserves the chance to survive leukaemia—regardless of where they are born. With global solidarity and strategic support, we can narrow the survival gap and ensure life-saving innovation reaches all corners of the world.

Yours faithfully

Vaskar Saha, MBBS, DCH, MD, PhD, FRCPCH, FRCPath