1st Invitation to manufacturers of medicinal products for treatment of childhood cancer to submit an Expression of Interest (EOI) for product evaluation to the WHO Prequalification Unit

To support national and global efforts to increase access and the affordability of care and treatment of childhood cancer, including through the Global Platform for Access to Childhood Cancer Medicines, WHO invites manufacturers of selected pharmaceutical products to submit Expressions of Interest (EOI) for product evaluation.

Article 1. Procedure for this Invitation to EOI

The current Invitation is published in accordance with the *Procedure for prequalification of pharmaceutical products*, adopted in 2001 by the 37th WHO Expert Committee on Specifications for Pharmaceutical Preparations, and amended subsequently as part of the 59th report of the Committee, published as Annex 4, No.1067 of the WHO Technical Report Series in 2026.

Assessment of product(s) submitted under this Invitation will include evaluation of:

- product dossiers, which must include product data and information as specified in the guidelines for submission (see Procedures & Fees)
- manufacturing sites, which must adhere to good manufacturing practices (GMP)
- clinical sites (if applicable), which must adhere to good clinical practices (GCP).

If evaluation demonstrates that a product and its corresponding manufacturing (and clinical) site(s) meet WHO recommended standards, it will be included in the list of prequalified medicinal products that are considered to be acceptable for procurement by UN organizations and others.

Article 2. Medicinal products included in the 1st Invitation

This 1st EOI is intended to encourage the availability of quality-assured medicinal products for childhood cancer through two complementary groups of products. The first group comprises priority age-appropriate formulations identified through WHO's paediatric drug optimization work and subsequent target product profile (TPP) development for childhood cancer medicines, with alignment to the WHO Model List of Essential Medicines and Model List of Essential Medicines for Children (EML/EMLc) where applicable. The second group comprises selected established products already recognized as essential medicines and included in this Invitation because of persistent access, supply, or formulation-related gaps affecting continuity and safety of childhood cancer care. The recommended active ingredients, dosage forms, and strengths appearing in this document have been identified by WHO's Department of Noncommunicable Diseases and Mental Health including through its hosted Global Platform for Access to Childhood Cancer Medicines. The medicines are targeted for treatment of childhood cancer, not a single disease but a broad category that includes multiple distinct types, each with unique biological characteristics, therapeutic targets, and clinical needs.

Interested manufacturers are encouraged to submit documentation for the medicinal products as specified below.

2.1 Priority age-appropriate formulations:

- Cyclophosphamide 5 mg orodispersible minitablets (in unit-dose packages) or 10 mg functionally scored

dispersible tablets as preferred; 5 mg dispersible tablets as alternative.
- Etoposide 10 mg minitablets or coated multiparticulates (in unit-dose packages) as preferred; 5 mg minitablets or coated multiparticulates (in unit-dose packages) as alternative.
- Mercaptopurine 10 mg scored dispersible tablets as preferred; 10 mg dispersible tablets as alternative.
- Methotrexate 2.5 mg orodispersible minitablets as preferred; 2.5 mg dispersible tablets as alternative.
- Procarbazine 20 mg scored dispersible tablets as preferred; 10 mg dispersible tablets as alternative.
- Temozolomide 20 mg scored dispersible tablets as preferred; dispersible tablets 10 mg as an alternative.

Manufacturers interested in developing multiparticulate products (e.g. orodispersible minitablets or sprinkles) should contact PQT/MED indicating the intended dosage form, presentation and dose for administration.

2.2 Selected established products addressing critical access gaps:
- Pegaspargase 750 units/mL solution for injection/infusion in 5-mL vial.
- Asparaginase 10,000 units powder for solution for injection (intramuscular use).
- Hydrocortisone (sodium succinate) 100 mg powder for solution for injection (preservative-free).
- Dactinomycin 500 mcg powder for solution for injection.
- Vincristine 1 mg/mL solution for injection in 1-mL or 2-mL single-dose vial.
- Cytarabine 100 mg/mL solution for injection, preservative-free, in 1-mL, 5-mL, 10-mL or 20-mL vial.

Article 3. How to submit an EOI

In order to submit an expression of interest for product evaluation, the manufacturer must send the required documentation, arranged according to the information provided on the WHO Prequalification Unit – Medicines Assessment Team (PQT/MED) of website at https://extranet.who.int/pqweb.

Article 4. Quality assessment procedure following submission of an EOI by a manufacturer

The quality assessment is undertaken to assess whether the pharmaceutical product being evaluated meets the requirements recommended by WHO, and is manufactured in compliance with good manufacturing practices (GMP).

The procedure established by WHO for quality assessment incorporates:
- general understanding of the production and quality control activities of the manufacturer;
- assessment of product data and information on safety, efficacy and quality submitted by the manufacturer, including product formulation, manufacture and test data and results;
- assessment of the manufacturing site's adherence to GMP, and its consistency in production and quality control of starting materials, with specific emphasis on active pharmaceutical ingredients, and finished product;
- assessment of clinical testing units or organizations (i.e. parties performing one or more clinical trials with the product) for compliance with good clinical practices and good laboratory practices, as appropriate;
- random sampling and testing of medicines supplied.

Previous evaluation conducted by the relevant National Drug Regulatory Authority (NDRA) may be taken into account during the evaluation conducted by WHO, provided that the NDRA has expertise in the product area. If appropriate, the relevant NDRA may be invited to collaborate with WHO on the quality assessment. Any manufacturer who submits a product for evaluation, is therefore encouraged to authorize its NDRA to discuss relevant product files with WHO representatives, during assessments and inspections, if required (subject to appropriate confidentiality provisions, if necessary).

Once WHO is satisfied that quality assessment has been completed for the manufacturer of the relevant starting materials, the finished pharmaceutical product, and the clinical testing units, and that the product meets WHO recommended standards, the product (as produced at the specified manufacturing site) is added to the WHO List of Prequalified Medicines.

Article 5. References and further information

World Health Organization Model List of Essential Medicines for Children – 10th list, 2025. Geneva: World Health Organization; 2025. Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/B09475

Paediatric drug optimization standard procedure. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/9789240039520

Accelerating the development of priority formulations in childhood cancer: target product profiles for paediatric formulations of cyclophosphamide, etoposide, mercaptopurine, methotrexate, procarbazine, temozolomide. Geneva: World Health Organization; 2025. Licence: CC BY-NC-SA 3.0 IGO.
https://www.who.int/publications/i/item/9789240116092

For further information on the WHO Prequalification Unit (PQT), please visit PQT's website at: Home | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control). Should you have any questions relating to the procedure for responding to an EOI, please write to the WHO Prequalification Unit at: prequalassessment@who.int Your question(s) will be directed to the prequalification team member who can best advise you.