

DISEASE BURDEN Breast cancer is the most common cancer in women and the second most common cancer worldwide. In 2022, there were over 2.29 million new cases of breast cancer in women. In LMICs, the majority of the patients are diagnosed at an advanced/metastatic stage and at least 30% of cases are characterised by overexpression of human epidermal growth factor receptor 2 (HER2 positive). INTELLECTUAL PROPERTY LANDSCAPE **CLINICAL RELEVANCE** Cancer-free survival is significantly improved in HER2-positive breast cancer patients who receive one year of trastuzumab treatment after adjuvant chemotherapy. The subcutaneous administration method is quicker, saving time and money to health systems, and is preferred by patients compared to the intravenous formulation. **TRASTUZUMAB SUB-CUTANEOUS** ONCOLOGY BREAST CANCER **SERVICE DELIVERY ENABLERS** REGULATORY Roche Diagnosis of breast cancer is provided in the public health sector in many LMICs, but a high proportion of cases is only

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detected at an advanced/metastatic stage of the disease. Generic companion treatments are usually available. The

subcutaneous formulation could simplify service delivery and

enable more people to be treated with the existing health

Complex manufacturing process since product is a monoclonal antibody. Aseptic processing is required. Occupation exposure band (OEB) level 3, manufacturing precautions necessary. Hyaluronidase, a biologic, is added as excipient. There are no anticipated challenges in relation to final packaging. Shelf life is 21 months under refrigeration.

The product is approved by stringent regulatory authorities. Potential sublicensees of trastuzumab subcutaneous could rely on mechanisms like Swissmedic MAGHP, EU-M4all or WHO PQ (if included in pilot program) for quality assurance. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment needs to be done. Phase III clinical trial waiver might be possible if there is already an approved intravenous product by the applicant.

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While biosimilar formulations of intravenous trastuzumab are available in many LMICs, subcutaneous formulation availability is very limited and hence its access in many LMICs, despite its advantages for patients and health systems.