Establishing Quality Product Supply of Chlorhexidine for Umbilical Cord Care through Local Production

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Major supply-side strategies

- Working with a global manufacturer.
- Working with local/regional manufacturers and establishing regional production hubs in selected countries.
Working with local/regional manufacturers

- Increasing production capability and capacity in low- and middle-income countries (LMICs).
- Existence of manufacturers with regional distribution network.
- Opportunities for further local capacity development.
- Product characteristics suitable for local production.
- Tailoring to local needs (e.g., packaging).
Ensuring product quality is a multi-layered and multi-disciplinary effort

Regulatory authority

Manufacturers

Procurers and providers

Acquisition of raw materials from quality sources

Production of the finished product in compliance with GMP

Product release after proper QC

Registration according to in-country regulations

Pre-purchase/sale inspections

Proper use
Select and work with qualified and committed manufacturers in countries where local production is feasible.

Develop standard information and materials for use by manufacturers, regulators, and procurers.
Three major steps to establish supply of quality product in LMICs

1. Assess the optimal way to establish product supply.
2. Select qualified and committed manufacturers in countries where local production is feasible.
3. Assist selected manufacturers to produce and register a quality chlorhexidine product.
Assessing the optimal way to establish product supply

- Assess the optimal way to establish product supply.
- Select qualified manufacturers in countries where local production is feasible.
- Assist selected manufacturers to produce and register a quality chlorhexidine product.

**Capability and capacity of pharmaceutical companies**
- Strength of pharmaceutical industry.
- Experience in producing gels and/or solutions or chlorhexidine-based products.

**Affordability**
- Domestic market size.
- Duties on imported API and other raw materials.

**Sustainability**
- Domestic market size.
- Possibility of exporting.
Selecting qualified and committed manufacturers

Assess the optimal way to establish product supply.

Select qualified and committed manufacturers in countries where local production is feasible.

Assist selected manufacturers to produce and register a quality chlorhexidine product.

- Issue an expression of interest (EOI).
- Send a questionnaire to manufacturers who respond to the EOI to select a short list of manufacturers.
- Perform on-site manufacturing facility assessment and business due diligence to select manufacturers that qualify for further technical assistance.
Assisting manufactures until product registration

- Assess the optimal way to establish product supply.
- Select qualified and committed manufacturers in countries where local production is feasible.
- Assist selected manufacturers to produce and register a quality chlorhexidine product.

- Perform in-depth GMP assessment and create corrective and preventive action (CAPA) plans.
- Follow up with manufacturers to ensure that CAPA plans are properly implemented.
- Assist with product development if required.
- Assist creation and submission of regulatory dossiers if required.
2015 status

Countries which have local production
Countries which decided to import the product

PATH and the Promoting the Quality of Medicines (PQM) program implemented by the US Pharmacopeial Convention (USP) are working to establish local and regional manufacturing hubs for chlorhexidine in Asia and Africa.
Commercial availability of 7.1% chlorhexidine digluconate

- **Solution**
  - UNICEF Supply Division catalogue
  - ACI Limited (Bangladesh)

- **Gel**
  - Drugfield Pharmaceuticals Ltd. (Nigeria)
  - Lomus Pharmaceuticals Pvt. Ltd. (Nepal)
Documents created for manufacturers, procurers, and regulators

- Monographs
  - Monograph for chlorhexidine gluconate topical solution included in USP-NF.
  - Monograph for chlorhexidine gluconate topical gel currently available for public comment in PF on USP website.

- Standardized patient information leaflet.
- Key consideration for procurers.
Welcome to the chlorhexidine for umbilical cord care topic page. This page provides the latest news, resources, multimedia and blogs on the use of chlorhexidine for umbilical cord care—a safe and effective intervention to prevent neonatal infection. This intervention is low cost and can be integrated into existing newborn care programs and platforms.

Browse the resource center on the right to find resources, guidelines and tools aimed to support program managers, policymakers and stakeholders in countries where early implementation of chlorhexidine is possible.
Thank you!

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http://www.healthynewbornnetwork.org/page/chlorhexidine-umbilical-cord-care-hub