Situation Analysis of the Domestic Production of Medicines in Paediatric Dosage Forms

Introduction

Objective
To conduct a situation analysis of the domestic production of medicines with an emphasis on paediatric dosage forms.

Scope
The focus of the study will be on domestic manufacturers. The situational analysis will serve as a first step in assessing the technical capacity of domestic pharmaceutical manufacturers to produce paediatric formulations/dosage forms of medicines. It will not consist of a complete situation analysis and in-depth appraisal of the technical feasibility of such production.

A list of 16 target paediatric medicines have been identified as the focus of the study. Data will be collected on the current domestic production of these products as well as other medicines in the same pharmacological class or in paediatric formulation.

Expected output
WHO will prepare a summary report of the data collected. It will include a mapping of domestic manufacturers in a given country, and for each, a list of the products currently manufactured that are included on, or have relevance to, the list of target paediatric medicines. In addition, a limited set of qualitative information will be collected on the technical feasibility of domestic manufacturers to produce to priority paediatric medicines. Each summary report will be provided through the WHO country office to the Ministry of Health.

Methods
Data collection will occur through visits or via email to domestic pharmaceutical manufacturers. Three generic data collection forms have been developed and should be completed for each domestic manufacturer:

- Data Collection Form - Part 1: "Background Information on Manufacturer" (complete one per Manufacturer)
- Data Collection Form - Part 2: "Manufacturing and starting materials" (complete one per Manufacturer)
- Data Collection Form - Part 3: "Potential to produce additional paediatric dosage forms" (complete one per Manufacturer)
- Data Collection Form - Part 4: "Product Information" (complete one per Manufacturer)
Data Collection Form - Part 1:
Background Information on Manufacturer

• Name of Manufacturer

• Address of Manufacturer

• Contact Person who provided information
  Name:
  Phone:
  Email:

• Address(es) of manufacturing site(s), if different from above

• Date Company was founded/established

• Year manufacturing site was built and any modifications

• Ownership structure (private, state, public, mix). Owned by another company?

NA = not applicable, NK = not known
• Does your company undertake contract manufacture for other companies?

☐ Yes  ☐ No

• Do you sub-contract to other companies?

☐ Yes  ☐ No

If Yes, please list products and/or services:

• What was the company's total revenue last year (specify currency)?

• Who are the company's customers? Tick all that apply and indicate approximate proportion of total volume sold (currency).

☐ Domestic: %

☐ Government: %

☐ Private Sector: %

☐ Other (e.g. NGOs, please specify): %

☐ International Donors: %

☐ Export: %

• What are the company's production activities? Tick all that apply.

☐ primary (manufacture of Active Pharmaceutical Ingredients (APIs) and intermediates)

☐ secondary (finished dosage forms)

☐ tertiary (packaging and labelling of products)

• How many people are employed the main manufacturing site?

total:

in production:

in quality control:
• Do you have any in-house research and development capacity?
  □ Yes □ No
  If Yes, please list products and/or services:

• Indicate the GMP standards with which the company complies:
  □ WHO
  □ PIC/EU
  □ FDA
  □ other:

• Dates of last two inspections by the National Regulatory Authority:

• Authorities other than the National RA who have inspected the company:

• Are you currently receiving techn./financial support from external agencies?
  □ Yes □ No
  If Yes, please describe (including type of support and current status):
Data Collection Form - Part 2:
Manufacturing and starting materials

• If your company is manufacturing penicillins or other beta-lactam products, does this production take place in separate building provided with its own air-handling system?

☐ Yes
☐ No
☐ Not manufacturing beta-lactam products.

• Are there any additional products that you are licensed to produce but are not producing?

☐ Yes
☐ No
☐ If yes, please list and explain reasons for not producing (e.g. lack of raw materials, supply chain problems, no sterile manufacturing capacity, lack of trained staff, change in recommended treatment):

• Starting materials sources for the company's major products?
Data Collection Form - Part 3:
Potential to produce additional paediatric dosage forms

- What additional technical requirements would be needed to add/change current production to include additional paediatric formulations and dosage forms: dispersible tables, oral dispersible tablets, suspensions and injections?
  (For example, human resources - number and skills, equipment purchase and maintenance, special storage requirements, etc.)
• More specifically, what would be required to change production from a:

(a) tablet to a dispersible tablet or oral dispersible tablet of the same medicine?

(b) suspension of one medicine to a suspension of a different medicine?

(c) injection of one medicine to an injection of a different medicine?

(d) package and label of an existing product to a paediatric product?

(e) tablet to a granule formulation in a sachet of the same medicine?
Data Collection Form - Part 4: 
Product Information

For each product listed below (Target Medicines for Paediatric Use) and any others in the same pharmacological class, please complete the "Product Information" pages.

<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Beta-lactam antibacterials, penicillin</td>
<td>• Amoxicillin</td>
</tr>
</tbody>
</table>

Product (INN / Brand Name):

Dosage Form / Strength:

Finished Product Specifications:

- [ ] British Pharmacopoeia (BP)
- [ ] European Pharmacopoeia (EP)
- [ ] Other - specify (e.g. "in-house"):  
- [ ] International Pharmacopoeia
- [ ] United States Pharmacopoeia (USP)

Status of Registration:

- [ ] Registered and currently marketed
- [ ] Registered but not marketed
- [ ] Registered for export only
- [ ] Not registered

- Number of Units produced per year:
- List any other countries where product is currently registered and marketed:

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<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Antimalarials</td>
<td>• Artemether + Lumefantrine</td>
</tr>
</tbody>
</table>

Product (INN / Brand Name):

Dosage Form / Strength:

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<tbody>
<tr>
<td>• Antimalarials</td>
<td>• Artesunate + Amodiaquine</td>
</tr>
</tbody>
</table>

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Dosage Form / Strength:

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<td>• Antimalarials</td>
</tr>
<tr>
<td></td>
<td>• Artesunate + Mefloquine</td>
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<tr>
<td></td>
<td>• Antimalarials</td>
</tr>
<tr>
<td></td>
<td>• Artesunate + Sulfadoxine / Pyrimethamine (SP)</td>
</tr>
</tbody>
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<tr>
<td>• Beta-lactam antibacterials, other</td>
<td>• Ceftriaxone</td>
</tr>
</tbody>
</table>

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**Dosage Form / Strength:**

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<tr>
<td>• Antibacterials</td>
<td>• Cotrimoxazole</td>
</tr>
</tbody>
</table>

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**Finished Product Specifications:**
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- Other - specify (e.g. "in-house"):  

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<tbody>
<tr>
<td>• Iron preparations</td>
<td>• Ferrous salt</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td>Product (INN / Brand Name):</td>
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<table>
<thead>
<tr>
<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Antibacterials</td>
<td>• Gentamicin</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>Product (INN / Brand Name):</td>
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</tr>
</tbody>
</table>
### Pharmacological Class

<table>
<thead>
<tr>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Drugs for treatment of tuberculosis</td>
</tr>
<tr>
<td>• Isoniazid</td>
</tr>
</tbody>
</table>

#### Product (INN / Brand Name):

#### Dosage Form / Strength:

#### Finished Product Specifications:

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#### Comments:

### Pharmacological Class

<table>
<thead>
<tr>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Electrolytes with carbohydrates</td>
</tr>
<tr>
<td>• Oral rehydration solution (ORS)</td>
</tr>
</tbody>
</table>

#### Product (INN / Brand Name):

#### Dosage Form / Strength:

#### Finished Product Specifications:

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<th>Pharmacological Class</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Other analgesics and antipyretics</td>
<td>• Paracetamol</td>
</tr>
</tbody>
</table>

Product (INN / Brand Name):

Dosage Form / Strength:

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<tbody>
<tr>
<td>• Antiepileptics</td>
<td>• Phenobarbital</td>
</tr>
</tbody>
</table>

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Dosage Form / Strength:

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</thead>
<tbody>
<tr>
<td>• Adrenergics, inhalants (drugs for obstructive airway disease)</td>
<td>• Salbutamol</td>
</tr>
</tbody>
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Product (INN / Brand Name):

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<tbody>
<tr>
<td>• Other mineral supplements</td>
<td>• Zinc</td>
</tr>
</tbody>
</table>

Product (INN / Brand Name):

Dosage Form / Strength:

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- [ ] British Pharmacopeia (BP)
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**Pharmacological Class** | **Medicine**
---|---
| |

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