MI/UNICEF joint TECHNICAL QUESTIONNAIRE FOR PHARMACEUTICAL MANUFACTURERS

Note to applicant: This questionnaire must be completed for each manufacturing site involved in the supply of the products to MI-UNICEF. Please also note that answers are not limited to the space provided in the questionnaire. If necessary, attach answers in a separate document.

1. GENERAL INFORMATION

- Name, address, telephone, email, fax, Internet address of the company:

2. AFFILIATES

- If the company is owned by another company, or belongs to a group of companies, please indicate your position within the structure:

3. REGULATORY ISSUES

3.1. **Good manufacturing practice**

- Indicate the GMP standards (WHO, PIC-S/EU, FDA or other) with which the company complies:

3.2. **Manufacturing licence for medicinal products**

- Please list the pharmaceutical dosage forms you are licensed to manufacture by the National Drug Regulatory Authority and attach a copy of the Manufacturing licence(s) or GMP certificate (it must indicate dosage forms manufactured):

3.3. **Inspection**

- Date of last inspection by the National Drug Regulatory Authority:

- Please attach a copy of the last inspection report by the National Drug Regulatory Authority if it can be made available for review by MI/UNICEF on a confidential basis.

- Names of all other Regulatory Authorities and International Organisations who have inspected the company. Please also state the outcome of the inspection:

- Please attach a copy of the last inspection report from other Regulatory Authorities or International Organisation if it can be made available for review by MI/UNICEF on a confidential basis. Comments (if any):

4. MANUFACTURING

4.1. **Manufacturing site**

- Please state all addresses at which manufacturing of pharmaceutical products takes place, and indicate which year the factory was built (complete one questionnaire for each site):

4.2. **Personnel**

- Please indicate the name and the education of the following key staff:

  - Managing director:
  - Production Manager:
  - Quality Assurance Manager:
  - Number of personnel in total:
  - Number of personnel in production:
  - Number of personnel in quality control:

4.3. **Ventilation system**

- Please indicate whether the manufacturing areas are equipped with controlled ventilation systems:

☐Yes ☐No

4.4. **Quality Control**

▪ Chemical laboratory	☐in-house	☐contracted out
▪ Biological laboratory	☐in-house	☐contracted out
▪ Microbiological laboratory	☐in-house	☐contracted out

4.5. **Contract manufacture**

- Please indicate if you undertake contract manufacture for other companies:

☐Yes ☐No

- Do you subcontract to other companies?

☐Yes ☐No

If yes, please list products and/or services and be reminded this questionnaire must be completed for each manufacturing site involved in supply of products to MI/UNICEF.

4.6. **Sterile products:**

Do you manufacture sterile products?

☐Yes ☐No

Which Method of sterilisation is used:

Is aseptic manufacturing processes simulated with media fills twice a year for product time and size? ☐Yes ☐No

4.7**. Beta-lactames**

Do you manufacture penicillins or other beta-lactam products?

☐Yes ☐No

If yes, does this production take place in separate buildings?

☐Yes ☐No

4.8. **Recalls**

- Do you have a recall procedure? ☐Yes ☐No
- Please indicate significant product complaints and any recalls the last three years:

4.9. **Production capacity**

Product	No of units per year	Last years' production - units
Tablets		
Capsules		
Ampoules		
Vials, liquids		
Vials, dry powder		
Vials, lyophilized		
Ointments		
Liquids		
Powder for oral suspensions		
Suppositories		
Penicillin, tablets/capsules		
Penicillin, powder for oral suspension		
Penicillin, powder for injection		
Other, specify		
Other, specify		

- Is production capacity figures based on one or more shifts? (Tick in appropriate box)

☐ 1 ☐ 2 ☐ 3

☐ Other, (please specify):

5. PRODUCTS

5.1 **Product licences**

- Please enclose a list of all products manufactured by your company and authorised for sale on the domestic market (country of origin). Comments (if any):

- For each licensed product, please categorise as follows:
  - The product is marketed on the domestic market.
  - The product is licensed but not marketed on the domestic market.
  - The licence is for export only

- Kindly also list licences for each product held in other countries:

- Please indicate how much in percentage your export is of the total production:

- Please also list the name of any contract manufacturer, when a product not is fully manufactured by your company.

- If possible, please attach an indicative price list. Comments (if any):

5.2. **Documentation**

- The following product documentation must upon request be available for all products offered to MI/UNICEF:
  - Product composition - master formula
  - Batch manufacturing record
  - Starting materials specification
  - Finished product specification
  - Validation report
  - Stability report
  - Packaging and labelling specifications
  - Annual Product Review

- Please indicate if this documentation is NOT available for any of the products on the list, point 5.1. :

5.3. **Samples**

- Are you willing to provide samples of finished products and batch documentation (on a confidential basis) if requested? ☐Yes ☐No

5.4. **Starting materials**:

- Indicate approved starting material sources for the company's major products and indicate if approved DMFs or Certificates of suitability of the Monograph of the European Pharmacopoeia are available:

- How is it ensured that Active Pharmaceutical Ingredients (APIs) are manufactured in accordance with GMP?

6. GMP INSPECTION

- Can MI/UNICEF or any other representative designated by MI/UNICEF perform an inspection of the Manufacturing site? ☐Yes ☐No

- Can the National Drug Regulatory Authority participate as observers in the audit? ☐Yes ☐No

- Please attach a Site Master File (PIC-S format). If not attached please indicate why it is not attached:

- May MI/UNICEF share the inspection report with its partners WHO Geneva, MSF France, ICRC Geneva and PIC-S member states upon request? (Your company will be notified in case the report is shared.) ☐Yes ☐No

7. OTHER INFORMATION

Contact person for MI/UNICEF:

Email:

Add any other information:

I hereby certify that the information given in this questionnaire and the attachments is correct.

Date:

Title:

Name:

Signature: