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**GUIDELINES on GMP INSPECTION OF FOREIGN PHARMACEUTICAL  
MANUFACTURING PLANTS USE in UGANDA  
(February 2007)**

**GUIDING PRINCIPLES/POLICY**

- 1) All pharmaceutical-manufacturing sites at which human and veterinary drug products (finished pharmaceutical products, biologicals, vaccines, medical devices, herbal medicines, etc) used in Uganda are manufactured (Storage of raw and packaging materials, dispensing, formulation, processing, packaging, quality control and release) shall be subject to **cGMP inspection by National Drug Authority before the drugs are registered and at least once every three years.**
- 2) The current Good Manufacturing Practices (cGMP) Guidelines as published by the World Health Organization (WHO) and NDA statutory requirements for manufacture of drugs shall be the basis against which National Drug Authority (NDA) shall inspect local and foreign manufacturing sites for GMP compliance.
- 3) The Drug Inspectorate Department of National Drug Authority shall coordinate cGMP inspection of all local and foreign pharmaceutical sites at which human and animal drug products used in Uganda are manufactured.
- 4) Each site of manufacture shall be inspected by at least two qualified cGMP inspectors for at least two days (depending on the number of manufacturing lines at each site) using the approved cGMP Inspection checklist.
- 5) The inspection shall be announced and based on all plant processes, systems and production lines.

**Criteria for approval**

- 6) A site shall be considered **compliant** if it obtains:

- a) **An average score of ≥70% in the general sections** as outlined in the inspection checklist (quality management and personnel, standard operating procedures, self inspection, premises and equipment, warehousing areas, dispensaries and Quality control/Assurance). (See “*Guide to Inspector on Use of GMP Inspection Checklist*” for details).
  - b) **A score of ≥70% in each production line.**
  - c) **No critical observation** in the general sections or each production line following classification of all deficiencies as critical, major and minor (See “*Guidelines for Risk Classification of cGMP Non-Compliances*” for details).
- 7) Major and Minor deficiencies may be resolved through submission of written corrective action but **Critical deficiencies can only be resolved through a re-inspection**. The re-inspection shall be after submission of corrective action and an application plus payment of the inspection fee. All the general sections of the facility must be re-inspected.
- 8) NDA shall, through exchange of information and working experience over time, **identify sites/companies with consistent high profile of cGMP compliance and Drug Regulatory Agencies (DRAs)/Institutions with cGMP Inspection procedures and competencies that meet NDA guidelines** for the purpose of establishing mutual recognition agreements (MRAs) or using their regulatory decisions. NDA shall thereafter either conduct joint inspections with, or recognize cGMP inspection reports from, such willing DRAs/Institutions. **All sites in countries with no MRAs with Uganda/NDA must be inspected at least once by NDA Inspectors.**
- 9) Risk management principles shall be used in prioritizing sites for cGMP inspection. Priority for cGMP inspection shall be given to companies/sites:
- a) From all countries with weak DRAs or DRAs of unknown strengths.
  - b) From countries with strong DRAs that supply a large number or a large volume of products. (***i.e. ≥3 products per site***) or highly GMP sensitive products.
- 10) A combination of the following documents may be used to assess and accept the GMP status of *companies/sites/production lines in countries with strong DRAs* which may not be inspected immediately either as a result of existing mutual recognition agreements, after the first mandatory GMP inspection or as a result of prioritization described above:
- a) Evaluation of cGMP certificate and/or manufacturing licence issued by a strong DRA/Institution.
  - b) Evaluation of a Site Master File (SMF) approved by a strong DRA/Institution.
  - c) GMP inspection report (product based or plant based) from the local Drug regulatory agency or a strong international drug regulatory agency
  - d) Photographs of any new room or equipment not used at the time of the previous inspection

- e) One Batch Manufacturing Record together with the master batch record including the packing and analytical parts for each dosage form applied for produced within the past one year.
- f) Any combination of the above as deemed necessary and approved by NDA
- 11) For the purposes of these guidelines the DRAs of the following countries that undertake independent product review shall be considered strong:
- a) PIC/S= Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme participating regulatory authorities ([www.picscheme.org](http://www.picscheme.org)):
- |                         |                        |                          |
|-------------------------|------------------------|--------------------------|
| ▪ <i>Australia</i>      | ▪ <i>Hungary</i>       | ▪ <i>Romania</i>         |
| ▪ <i>Austria</i>        | ▪ <i>Iceland</i>       | ▪ <i>Singapore</i>       |
| ▪ <i>Belgium</i>        | ▪ <i>Ireland</i>       | ▪ <i>Slovak Republic</i> |
| ▪ <i>Canada</i>         | ▪ <i>Italy</i>         | ▪ <i>Spain</i>           |
| ▪ <i>Czech Republic</i> | ▪ <i>Latvia</i>        | ▪ <i>Sweden</i>          |
| ▪ <i>Denmark</i>        | ▪ <i>Liechtenstein</i> | ▪ <i>Switzerland</i>     |
| ▪ <i>Finland</i>        | ▪ <i>Malaysia</i>      | ▪ <i>United Kingdom</i>  |
| ▪ <i>France</i>         | ▪ <i>Netherlands</i>   |                          |
| ▪ <i>Germany</i>        | ▪ <i>Norway</i>        |                          |
| ▪ <i>Greece</i>         | ▪ <i>Poland</i>        |                          |
|                         | ▪ <i>Portugal</i>      |                          |
- b) ICH = International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use participating regulatory authorities ([www.ich.org](http://www.ich.org))
- i) European Union(EMEA)\*
- ii) Japan (MoH)
- iii) United States (USFDA)
- \* Members include: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Slovakia, Slovenia, Spain, Sweden, The Netherlands and United Kingdom.
- c) Any other that may be approved by NDA from time to time.

### **Fees**

- 12) A GMP Inspection fee per facility/site shall be charged from the applicant to cover the cost of inspection and assessment including but not limited to administrative costs, air tickets, per diem for inspectors and other incidentals. This fee shall be paid to NDA before a company is put on the inspection schedule. Cancellation of the inspection schedule by the applicant after the company's confirmation shall lead to forfeiture of the inspection fees.
- 13) The cGMP inspection fees shall be determined as follows:
- |  |                     |
|--|---------------------|
| a) Manufacturing sites within East Africa        | US \$2,000 per site |
| b) Manufacturing sites within the rest of Africa | US \$3,000 per site |

- c) Manufacturing sites outside Africa US \$4,000 per site
- d) Sites whose GMP status is approved using principles outlined in section 11 above shall still pay the applicable fee as NDA reserves the right to inspect the site any time.
- e) On special request and under exceptional circumstances, applicants with products that are manufactured at more than one site may be considered for a reduced fee **for the extra site(s)** if the extra site:
- i) **is located in the same country as the initial site** and,
  - ii) **does not fully manufacture any other product eligible for cGMP inspection that is or intended to be registered in Uganda,**
- according to the following criteria:

	<b>Processes at the site</b>	<b>East Africa</b>	<b>Rest of Africa</b>	<b>Outside Africa</b>
1	All processes at one site	\$2,000	\$3,000	\$4,000
2	Warehousing of raw materials up to finished bulk product	\$1,500	\$2,000	\$3,000
3	Final packaging, quality control and final release	\$1,000	\$1,500	\$2,000
4	Quality control and final release	\$500	\$750	\$1,000

- f) Sites that manufacture **orphan drugs** (as defined by WHO) with no other registered source and annual sales turnover in Uganda less than \$10,000 shall, on request and justification, either be inspected at a reduced fee and/or be evaluated using other methods as outlined in principle (11) above.
- g) Sites that manufacture vital drugs on the Essential Drug Lists of Uganda (EDLU/EVDLU) with no other or one registered source may, on written request and justification, be considered for inspection at a reduced fee and/or evaluation using other methods as outlined in principle (11) above.
- h) Payment of fees can be made by Bank Transfer to:

National Drug Authority Account no: 0240060034201  
Stanbic Bank Uganda Limited, Kampala

or by bank draft in favour of National Drug Authority

- 14) A company shall be placed on the schedule for inspection only after receipt of all the information specified in the “*Application for GMP Inspection*” and the appropriate fee.

### **The Inspection**

- 15) Inspection of a foreign pharmaceutical may be initiated through any of the following ways:
- a) Re – inspection after a period of three years from the date of the last inspection.
  - b) Direct application for GMP inspection or re-inspection by the manufacturer or his/her representative before any dossier is submitted or following a critical failure.

- 16) At least two months prior to the anticipated inspection trip, NDA shall send to the applicant through their Local Technical Representative (LTR) the form for "*Application for GMP Inspection*" accompanied by the respective invoice for inspection fees.
- 17) The following criteria shall be used in making a schedule out of those due for cGMP inspection:
  - a) Sites from which applications for registration (Dossiers) and/or inspection have been received.
  - b) Companies that were the first to apply for registration and/or inspection.
  - c) Company that were the first to pay for inspection.
  - d) Sites whose inspection would be crucial in making an ongoing regulatory decision or meeting an emergency or a public health priority.
  - e) Other companies may be included on the schedule in order to make a particular inspection trip cost-effective and geographically logical because of their proximity.
  - f) A balance shall be made between the available human resources for cGMP inspection and other operations of NDA.
- 18) Each inspection trip shall cover six (6) manufacturing sites, unless expressly authorized by the Executive Secretary/Registrar NDA.
- 19) The most current version of the *cGMP/Quality Assurance Audit Checklist* and the *Guide for the cGMP Inspector* shall be used in conducting and preparing the report of the inspection.
- 20) NDA shall communicate the findings of the cGMP audit and the decision of the Technical Committee to the management of the inspected sites within 10 working days following the discussion of the audit report.
- 21) The summary of the decisions of the Technical Committee and any corrective action from the applicant shall be presented to the Committee on the National Formulary for consideration and approval.
- 22) The management of the inspected site shall have a right to appeal the decision of the Technical Committee within one calendar month of communication of the decision.
- 23) The appeal shall be considered at the next scheduled meeting of the Technical Committee and subsequently the Committee on the National Formulary (CNF).
- 24) The decision of the Authority (NDA Board) on the advice of the Committee on the National Formulary on the appeal shall be the final NDA position on the cGMP status of the inspected site.