RISK CATEGORIZATION OF FOREIGN MANUFACTURING FACILITIES

INTRODUCTION

This categorization has become necessary to allow proper planning for the conduct of quality audits of these facilities and will also ensure that scheduling of facilities for inspection is done using a risk-based approach with facilities of higher risk categorization being scheduled and inspected first while those with lower risk categorization are inspected at a later date.

The facilities are categorized into four (4) levels with Level 4 being the highest risk level and Level 1 being the lowest. The criteria used for the categorization is as follows:

LEVEL 1

1. Facilities operating in Stringent Regulatory environments.
2. Multinational companies/Global brands.
3. Facilities having World Health Organization (WHO) GMP certification/Prequalified product.
4. Facilities operating in a Pharmaceutical Inspection Cooperation Scheme (PIC/S) member country.

LEVEL 2

1. Facilities with history of more than Two (2) satisfactory NAFDAC GMP audits.

LEVEL 3

1. Facilities that have had one satisfactory NAFDAC GMP audit.

LEVEL 4

1. No history of NAFDAC GMP audit and not falling in category 1 above.
2. History of unsatisfactory NAFDAC GMP audit or major deficiencies.
3. International alerts or product recalls from the facility.
4. Country categorization based on historic trends e.g. NAFDAC inspection history or other regulatory decision(s).

Marketing Authorization for registration applications from facilities in Levels 1 & 2 are to be granted while the inspection of these facilities by NAFDAC will be conducted at a later date.

Registration applications from facilities in Levels 3 & 4 will not be presented for approval until the facilities have been inspected by NAFDAC and the GMP is found satisfactory.

Facilities can migrate between levels based on the outcome of the NAFDAC inspection while two (2) unsatisfactory GMP audits of a facility will lead to inability to grant Marketing Authorization for products manufactured in those facilities.

In view of the foregoing, there is a need to obtain information on the status of foreign manufacturing facilities and as such, applicants for product registration will be required to provide necessary information on their intended manufacturers to enable categorization of the facilities. This is to be done through the completion of the **Facility Status Verification Form** at the point of submission of the registration application. These forms are to be forwarded to the relevant Inspection Directorates for categorization of the facilities.