APPENDIX 29

CERTIFICATE

1. CERTIFICATE OF PHARMACEUTICAL PRODUCT (CPP)

A CPP in the format recommended by WHO for a registered product can be applied by the PRH where such certificate is required by any country importing such product.

To apply a CPP, the PRH shall fill up completely and submit the online application form via the QUEST system.

A fee, as stated in **Appendix 9: Fees**, is payable on the issue of such certification.

Upon receipt of complete application, the certificate shall be issued within fifteen (15) working days.

For imported products, the following requirements shall be furnished, either a:

i) CPP from the competent authority in the country of origin; OR
*(**Note:** In the event a CPP is not available from the country manufacture, e.g. where a product is not licensed for sale in said country because its manufacturer is manufacturing under contract only for product owner from another country, the following alternatives may be considered: GMP Certification/ Manufacturing License for the manufacturer from the relevant competent authority, together with CPP from the country of the product owner; or CPP from country of release, if CPP from the country of the product owner is not available)*

ii) CFS and GMP from the relevant competent authorities is deemed acceptable by the Authority for health supplements and natural products only.

CPP shall be in the format of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce & be issued by the Health Authorities listed in the WHO Certification Scheme (*list is available from WHO website*: *http://www.who.int*).

CPP which is issued by EMA for products registered through the centralized procedure in EU will be accepted.

CPP issued by the manufacturer or other authorities are not acceptable.

If more than one manufacturer is involved in the manufacture of a product, GMP certification shall be available for all the manufacturers.

The Authority reserves the right to conduct an inspection on any manufacturing site.

Unless otherwise supported by justifications acceptable to the Authority, the following products are unlikely to be registered:

i) products not licensed/ certified for sale in the country of manufacture/ product owner;
ii) products manufactured for export only (imported products).

2. GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE

According to the CDCR 1984, compliance to Good Manufacturing Practice (GMP) is a prerequisite to the application of a Manufacturer's license, as well as product registration/ cosmetic notification.

GMP is a standard which shall be followed by the manufacturers to ensure that the products manufactured are safe, efficacious and of quality.

A GMP Certificate is issued for the purpose of exporting locally manufactured registered products. It endorses that the local manufacturer complies with the current GMP requirements. These certificates are required by overseas regulatory agencies for the purpose of product registration in their respective countries. Thus, when filling in the GMP Certificate application form, it is crucial for the company to provide the correct address of the overseas regulatory agency.

Upon complete application, a GMP certificate will be issued. A fee of RM50.00 is payable for the issuance of such certification.

The application of GMP Certificate by local manufacturers shall be submitted via the online QUEST system, while applications from foreign manufacturers that have been inspected by NPRA shall be submitted manually via *Borang BPFK-420 Permohonan Sijil Amalan Perkilangan Baik (APB) Pengilang Luar Negara.*