APPENDIX 29

CERTIFICATE

1. CERTIFICATE OF PHARMACEUTICAL PRODUCT (CPP)

The Certificate of Pharmaceutical Product (CPP) is a document issued by a competent authority for establishing the status of a pharmaceutical product under a national drug product licensing system. Competent authority refers to any local or national regulatory authority responsible for regulating the quality, efficacy, and safety of medicine. The CPP issued by other organizations or bodies, that the competent authority has appointed is also acceptable. The competent authority may issue a CPP for any product that has been registered locally if such a certificate is required by the Product Registration Holder (PRH) for the purpose of export.

On the other hand, a CPP from an exporting country may be required to support product registration in Malaysia. The CPP plays a crucial role in supporting the registration of imported medicinal products in Malaysia. The CPP serves as official documentation issued by the regulatory authority of the exporting country, confirming that the pharmaceutical product meets regulatory requirements and is authorized for sale in that country. The submission of CPP during the product registration application provides assurance to NPRA that the product has undergone evaluation and approval processes consistent with international standards, including confirmation that the product is manufactured in a facility compliant with Good Manufacturing Practice (GMP).

A. How to apply for a CPP

PRH may apply for a CPP in the format recommended by WHO for a registered product in Malaysia when such a certificate is required by any country importing the product.

To apply for a CPP, the PRH shall complete the online application form and submit it via the QUEST system.

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

The certificate shall be issued within fifteen (15) working days upon receipt of a complete application.

B. Submission of a CPP to support registration applications for imported products

A CPP is required at the point of submission for imported products. A CPP may serve as a reliance tool to confirm the quality, safety, and efficacy of a product hence this could facilitate the review process of such product and its registration approval in Malaysia.

If the CPP is to be provided, the following are applicable:

a) CPP from the competent authority in the country of origin (country of manufacture) in the format of the *WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce* or by the authorized body.

b) CPP issued by the manufacturer is not acceptable.

c) CPP that is valid at the time of submission. If the expiration date is not stated on the CPP, the CPP validity should not exceed 2 years from the date of issuance.

d) Both original and electronic CPPs issued by the NRAs are acceptable.

e) All information except for brand name/trade name reflected in the CPP must be applicable and consistent with the proposed product for the Malaysian market.

f) CPPs indicating that the product is solely for export only (not registered and not marketed in the exporting country) are not acceptable.

g) If more than one manufacturer is involved in the manufacture of a product and are intended to be registered in Malaysia but not stated in the CPP, GMP certification should be submitted for all the manufacturers. NPRA reserves the right to conduct an inspection on any manufacturing site when deemed necessary.

h) In the event a CPP from the country of origin is not available, for example when the product is manufactured under contract for a product owner from another country and the product is not licensed for sale in the manufacturing country, the following alternatives may be considered:
   i. CPP from the country of the product owner; OR
   ii. CPP from the country of release or CPP from DCA reference country, if CPP from the country of the product owner is not available.

i) CPPs with a declaration that the product is not marketed may be acceptable if:
   i. The CPP is issued by a competent authority; AND
   ii. Manufacturer declares in the declaration letter the reason for not marketing the product in the country. The acceptance of the reason for not marketing the product in the country is subject to NPRA's discretion

Note: Point i) is not applicable for non-scheduled poison (OTC), health supplements and natural products (excluding natural product with therapeutic claim and health supplement with disease risk reduction)

C. <u>Alternative documents in lieu of CPP to support registration applications for imported products</u>

a) If a CPP cannot be provided at the point of submission, the following documents can be considered as alternatives

i. An official approval letter or document by the competent authority that states the registration status of the product; AND
ii. Certificate of Free Sale (CFS) or proof that the product is marketed in the exporting country. If the product is not marketed in the exporting country, the manufacturer declares in the declaration letter the reason for not marketing the product in the country. The acceptance of the reason for not marketing the product in the country is subject to NPRA's discretion; AND
iii. The Summary of Product Characteristics (SmPC) or Package Insert (PI) approved by the competent authority

b) For non-scheduled poison (OTC), health supplements and natural products (excluding natural product with therapeutic claim and health supplement with disease risk reduction), a Certificate of Free Sale (CFS) and Good Manufacturing Practice (GMP) certificate from the relevant competent authorities are required as alternative documents.

D. <u>The submission of a CPP for product not registered in any other country</u>

a) Submission of a product registration without a CPP due to the fact that the product has not been previously approved in any country can be considered on a case-by-case basis depending on the country's need.
b) Prior to submitting the dossier, the applicant should submit an exemption request letter with justifications to the Director of NPRA. Subsequently, the applicant may request a pre-submission meeting to provide an overview of the product and regulatory submission plan in other countries (if any).
c) This requirement is not applicable for non-scheduled poison (OTC) products, health supplements and natural 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.*