

**DEPARTMENT OF HEALTH
PHARMACEUTICAL SERVICE
PHARMACEUTICALS REGISTRATION SECTION**

Appendix 1

CHECKLIST

Application for Product/Substance Registration

Please lodge this checklist and arrange the documents in the following order with your application form.

- | | Yes | No |
|--|--------------------------|--------------------------|
| 1. Is this a <u>priority</u> application? | <input type="checkbox"/> | <input type="checkbox"/> |
| (i). change of name, dosage form or active ingredient, please provide the original registration certificate of the existing product; or | <input type="checkbox"/> | <input type="checkbox"/> |
| (ii). change of product certificate holder, please provide a statement from manufacturer for the change. | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Copy of <u>business registration certificate</u> of applicant? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Have you provided evidence that the product is manufactured by a licensed manufacturer? (e.g. certified true copy of <u>manufacturer's licence</u>) | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Have you provide evidence of Good Manufacturing Practices (GMP) compliance of the manufacturer? (e.g. certified true copy of <u>GMP Certificate of the manufacturer</u>) | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Have you provided evidence that the product is allowed for sale in the country of origin? (i.e. original or certified true copy of <u>free sale certificate</u>) | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Is the product a <u>new</u> chemical or biological entity? | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Have you provided <u>clinical and scientific papers</u> as required? | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Have you enclosed one set of original (or prototype) <u>sales pack</u> (outer carton) and container label of each pack size of your product? | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Have you enclosed copy of <u>documents to support the indications</u> and other information in the package insert? (if any) | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Have you provided <u>samples</u> of your product as it will be sold to the purchaser? | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Have you provided information on both active and inactive ingredients of your product? (e.g. <u>complete master formula</u>) | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Have you provided the <u>specifications</u> issued by the manufacturer showing compliance with one or more of the following, unless otherwise justified: Pharmacopoeia of the People's Republic of China, British Pharmacopoeia, European Pharmacopoeia, International Pharmacopoeia, Japanese Pharmacopoeia and/or United States Pharmacopoeia. (e.g. in the case of a tablet, physical description, uniformity of weight, disintegration time, identification and assay of active ingredients, etc.) | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Have you provided the <u>method of analysis</u> of the product? | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Have you provided a <u>certificate of analysis</u> of a representative batch of the product? | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Have you provided <u>stability test data</u> (real-time/accelerated conditions) to justify the proposed shelf-life? | <input type="checkbox"/> | <input type="checkbox"/> |