

	TRADITIONAL AND COMPLEMENTARY MEDICINE DIVISION MINISTRY OF HEALTH
	APPLICATION GUIDELINE FOR EVALUATION OF PROPOSAL ON TRADITIONAL AND COMPLEMENTARY MEDICINE PRACTICE

1. OBJECTIVE

The purpose of this document is to explain the process of application for the evaluation of a proposal on any therapeutic or medicinal claims made for the purpose of treatment, prevention, curing, alleviating medical symptoms or diseases using any form of traditional and complementary medicine (T&CM) practice. Practitioners or individuals interested in substantiating claims towards a respective method of T&CM treatment or approach for the above mentioned intentions will have to submit the required documents for an evaluation to be conducted by the T&CM Division, Ministry of Health Malaysia.

2. RELATED LAWS AND JURISDICTION

Evaluation of the submitted documents will be conducted in accordance to the requirements of the following related laws and regulations.

2.1 Traditional and Complementary Medicine (T&CM) Act 2016

An act to regulate T&CM practice and practitioners in Malaysia. Based on the Traditional and Complementary Medicine (Recognized Practice Areas) Order 2017, currently there are seven recognized practice areas as follows:

1. Traditional Malay Medicine
2. Traditional Chinese Medicine
3. Traditional Indian Medicine
4. Homeopathy
5. Chiropractic
6. Osteopathy
7. Islamic Medical Practice

2.2 Poisons Act 1952 and Regulations

An act to regulate the import, possession, manufacture, compounding, storage, transportation, sale and use of Poisons.

2.3 Medical Device Act 2012

An act to regulate medical devices, the industry and to provide for matters connected thereto.

2.4 Medicines (Advertisement & Sale) Act 1956 and Regulations

An act to prohibit certain advertisements relating to medical matters and to regulate the sale of substances recommended as a medicine.

3. DOCUMENTS REQUIRED TO BE SUBMITTED

Applicants are required to submit the following documents in order for the evaluation to be conducted by the T&CM Division:

1. Application form for T&CM proposal evaluation (BPTK(AP)-BOR-01).
2. Proposal on T&CM Practice (Appendix A).
3. Supporting documents on literature to be evaluated as listed in reference segment of the proposal.
4. In cases where supportive documents are not originally in English or Bahasa Melayu, a copy of the document in its original language, accompanied by authenticated translation in English or Bahasa Melayu shall be submitted.
5. Proof of registration of products or herbs or devices related and referred to in the proposal document.
6. Completed and signed checklist (BPTK(AP)-BOR-02).

4. EVALUATION PROCESS

Applications received will undergo the following process:

1. Completed application forms are to be submitted to the T&CM Division through email at tcm@moh.gov.my.
2. Kindly complete the application form provided (BPTK(AP)-BOR-01) and use the proposal template (Appendix A) as a guide to submit your proposal.
3. An official response will be given within 24 working hours to acknowledge receipt of complete application documents.

4. Proposals submitted will be reviewed and evaluated against available evidence to support the claims made in the proposal during the time of evaluation.
5. During the process of evaluation, the T&CM Division may request for further details or supporting documents if deemed necessary.
6. Applicants will receive an official response from the T&CM Division on the outcome of the evaluation.
7. Enquiries relating to the application procedure or status may be forwarded to the T&CM Practice Section at 03-2279 8100 or email at tcm@moh.gov.my.

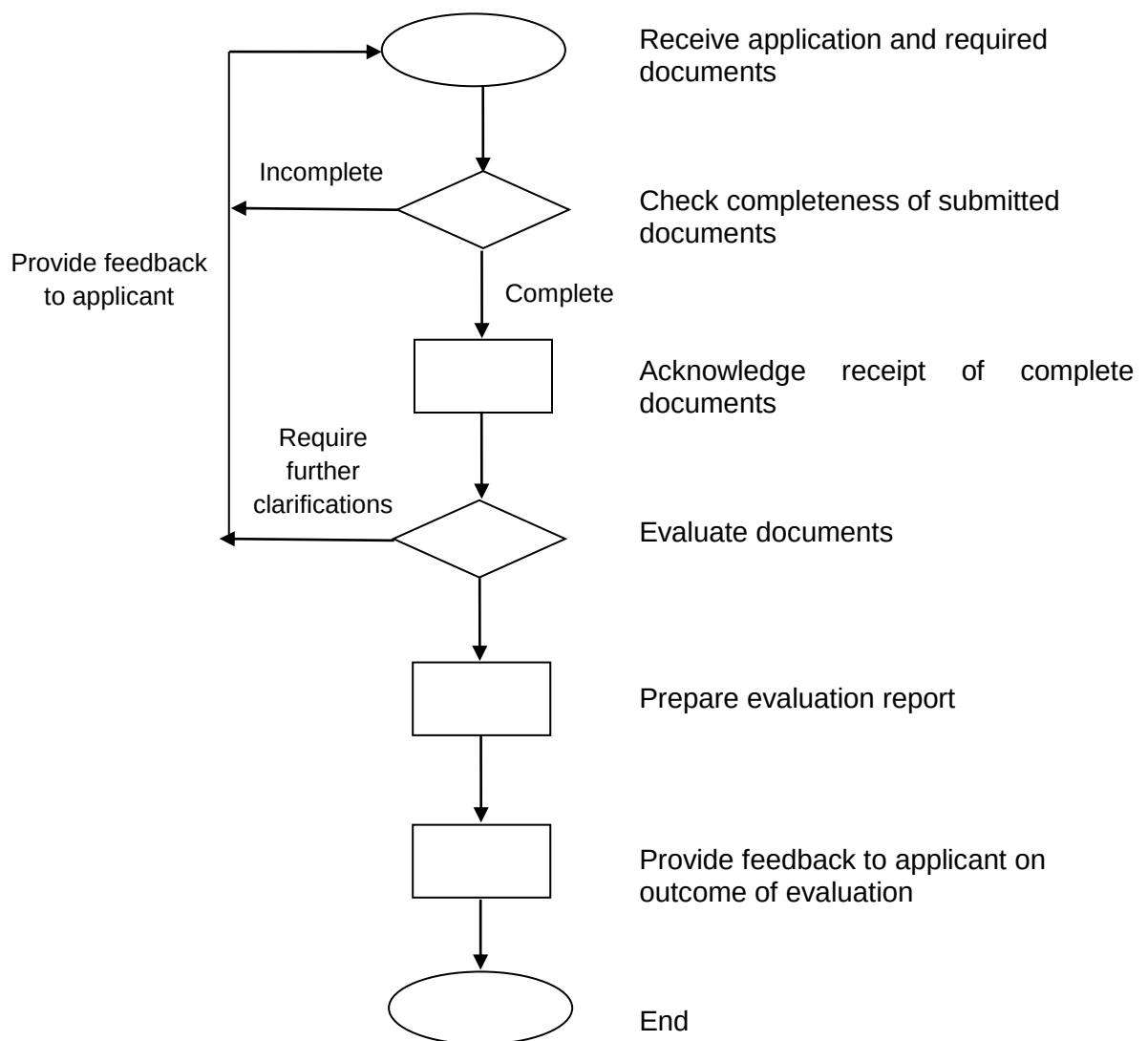


Diagram 1: Flow chart of evaluation process

*This guideline is subject to amendment from time to time without prior notification.