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Translation variations under legal constraints in the packaging information of traditional Chinese herbal medicine sold in Malaysia

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ABSTRACT



Chinese-English pharmaceutical-packaging translation facilitates the dissemination and acceptance of traditional Chinese medicines (TCMs) within the multilingual and multicultural context of Malaysia. However, awareness of TCMs beyond the Chinese community remains limited due to major factors including legal constraints imposed by drug regulatory authorities and challenges in translating product names and indications. Therefore, this article investigates the translation of packaging information for TCMs sold in Malaysia, where multiple cultures and languages interact. The study anchors itself on the translation procedures proposed by Vinay and Darbelnet (1958/1995). The article adopts a descriptive and comparative approach based on a sample of 36 TCM products obtained from the official websites of two local pharmacies. It reflects on how the legal requirements of the National Pharmaceutical Regulatory Agency (NPRA) impact what can or cannot be included in packaging. In essence, it examines how translation decisions are influenced by legal constraints and discusses the value of different translation approaches in light of these constraints. The significance of studying TCM translation under legal constraints in a specific market lies in ensuring regulatory compliance, safeguarding consumer safety, facilitating market access, preserving cultural sensitivity, and upholding professional standards and ethical practices within the Chinese-English pharmaceutical-packaging translation practice.


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Introduction

Traditional Chinese medicine (TCM), as a form of traditional medicine (TM), has been recognised by the World Health Organisation (WHO) (Pierre-Louis Lezot, 2014). In particular, the inclusion of TCM in the International Statistical Classification of Diseases and Related Health Problems (ICD) due to its lower cost and accessibility eventually help it become an integral part of global healthcare (Cyranoski, 2018). By 2023, TCM has been exported to 196 countries and regions (Chen, 2023), with its main markets primarily located in Asia, including Hong Kong SAR, Japan, Malaysia, South Korea and Indonesia (Lin et al., 2018). In this context, the Ministry of Health (MOH) Malaysia has established Traditional & Complementary Medicine (T&CM) units at MOH hospitals to integrate T&CM practices into the national healthcare system. This integration is structured through a mechanism with two schedules: Schedule 1 officially designates MOH hospitals that provide T&CM services (e.g. traditional massage, acupuncture, herbal therapy), and Schedule 2 describes the approved clinical indications for these services (e.g. acupuncture using traditional Chinese medicine for chronic pain, post stroke, Chemotherapy-induced nausea & vomiting) to ensure their standardised and safe application in patient care (Traditional and Complementary Medicine Division, 2024). Malaysia is a multi-ethnic country consisting of three major ethnic groups: Malays, Chinese, and Indians. According to the *National Health and Morbidity Survey 2015* (Institute for Public Health, 2015), about one-third of Malays (31%) and almost one-fifth of Indians (18%) reported having consulted a practitioner of T&CM at least once. Under Malaysia's T&CM Act 2013, T&CM practice explicitly includes traditional Chinese medicine (TCM) (Malaysia, 2013). Although NHMS 2015 does not break down prevalence by specific T&CM modality for each ethnic group, these figures suggest that TCM related products may reach a substantial non-Chinese audience, which highlights the need for clear English-language information on their packaging. However, TCM products still appear to have limited acceptance among the Malaysian population, and this seems to be a multifaceted issue. In addition to insufficient public knowledge (Mohiuddin et al., 2021), factors such as skepticism about their clinical efficacy (Traditional Chinese medicine needs proper scrutiny, 2017) and cultural perceptions (Kumar et al., 2015) also contribute to their reception. While these factors undoubtedly play a role in the overall reception of TCM, this study specifically examines how the difficulties in translating TCM product names and indications exacerbate these challenges in the Malaysian context. Coupled with the lack of equivalent terms in foreign languages, the difficulty increases and makes the translation of TCM a challenging task that deserves the attention and discussion of the academic community (Li, 1996).

TCM is a cultural heritage that the Chinese people have reserved and empirically applied (Wang et al., 2021), and is deeply rooted in Chinese traditional philosophy and culture (Cyranoski, 2018; Yee et al., 2005; Zou, 2015). The fundamental concepts of TCM encompass 阴阳 *Yin-yang*, 五行 *wuxing* 'Five components' or 'Five phases', 气 *Qi*, and the clinical practice of TCM bases itself on the notion of 辨证论治 (*bianzheng lunzhi*, which refers to treatment based on pattern differentiation). Pattern differentiation means comprehensive analysis of clinical information obtained through the four primary diagnostic procedures used in TCM, namely observation, listening, questioning, and palpation (World Health Organisation, 2022). Following that, it serves as a guide for the indication

and prescription of TCM herbal formulas (Fangji) (Traditional and Complementary Medicine Division, 2018).

Drugs in both Western medicine and Chinese medicine are controlled by their respective organisations. Drugs in Western medicine undergo rigorous clinical trials and approval procedures overseen by various regulatory bodies, such as the World Health Organisation (WHO), and national regulatory authorities. In China, TCM products are subject to stringent regulations by the National Administration of Traditional Chinese Medicine (NATCM), which requires clinical evidence to support claims of efficacy for certain diseases (Wang et al., 2021). In Malaysia, TCM products are regulated by the National Pharmaceutical Regulatory Agency (NPRA) and must meet safety and quality standards to be sold legally. However, unlike China's NATCM regulations, Malaysia's NPRA does not allow TCM products to advertise disease-specific curative claims unless they are scientifically validated like pharmaceuticals. For instance, a TCM product marketed in China may claim to 'treat hypertension' based on historical use and limited trials under the NATCM guidelines, but the same product in Malaysia would be limited to general wellness claims (e.g. 'supports cardiovascular health') unless proven through clinical studies prescribed by the NPRA. Consequently, health and treatment benefits stated on product packaging in China, often linked to disease-specific outcomes, may lack empirical validation or regulatory approval for such claims in Malaysia, making it difficult to reproduce these claimed benefits in the Malaysian context.

This study is conducted in Malaysia, where Malays (69.9%), Chinese (22.8%), Indians (6.6%), and other races (0.7%) constitute its population (Department of Statistics Malaysia, 2024). In Malaysia's multi-ethnic and multi-lingual context, legal regulations play a crucial role in shaping the packaging information of TCM products. As stated in the *Drug Registration Guidance Document* (DRGD, Third Edition, Sixth Revision 2023), 'product information must be in Bahasa Malaysia or English, and additional translation to another language is allowed' (NPRA, 2023, p. 39). This regulatory framework stipulates that packaging must be predominantly bilingual, usually with Chinese text (the source text, ST) and English text (the target text, TT), occasionally with Malay, the official language of Malaysia (CommonLII, 2019). While these legal specifications aim to ensure consistency and consumer protection, they also constrain the translation process. Through an analysis of products available in Malaysia, this article investigates how these regulatory restrictions lead to translation variations in TCM product names and indications, variations that may result in differences in the health and treatment benefits conveyed compared to those on Chinese packaging. The investigation utilises Jean-Paul Vinay and Jean Darbelnet's (1958/1995) category of translation procedures to classify and elucidate the translation decisions.

Situated in the context of Malaysia, this article aims to address the following research questions: (1) What are the legal constraints regulating TCM product names and indications for registration in Malaysia? (2) What are the methods employed in the English translation of product names and indications of TCMs in response to these regulatory constraints? (3) How do translation choices align with or deviate from these regulatory constraints?

Translation of TCM terms

In medical translation, one problem comes from the tendency for literal translation errors, which can lead to misinterpretation of medical terms and affect translation accuracy

(Norova Mavluda Fayzulloyevna, 2022). Other challenges faced include the complexity of medical terminology across languages and cultures, different genres of medical texts (such as research articles, patient fact sheets, and biomedical patents), and cultural differences in health beliefs and practices (Montalt et al., 2018). In the case of TCM, it is even more challenging when it comes to the translation of terms as ‘one single concept may have several expressions in English’ (World Health Organisation, 2007, p. 5).

There has been scholarly debate on the need to maintain the Chinese characteristics of TCM terms. Translators are advised to adopt a source-oriented approach that prioritises literal equivalents to preserve the conceptual and historical integrity of Chinese medicine terminology (Ye & Dong, 2017). This aligns with the *WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region (ISTTM, 2007)*, which stipulates that English translations ‘accurately reflect the original concept of Chinese terms’ (p.4). Unschuld (2003, 2010) similarly advocates a historically and philosophically faithful translation strategy and argues that key TCM terms (e.g. *Qi*, *Yin-yang*, *Zang-fu*) should be rendered through literal translation or transliteration. This approach emphasises the preservation of the indigenous conceptual framework of Chinese medicine and reinforces the source-oriented translation norms in the academic discourse of TCM.

However, translators must also reconcile these priorities with pragmatic demands for accessibility. Critics argue that ensuring the translated texts are comprehensible to the intended readers is of greater importance (Zhang & Dong, 2020), a view further supported by research highlighting the need to enhance accessibility for a broader audience by simplifying language and improving overall structure (Askehave & Zethsen, 2014), as most patients mainly follow product instructions to take medicine (Zou, 2015). In this regard, Lim et al. (2022) take a more balanced approach that incorporates major strategies of semantic translation, literal translation, and transliteration. Regarding the translation of TCM terms, there is considerable disagreement rather than consensus. Under Malaysia’s regulatory framework, where the National Pharmaceutical Regulatory Agency (NPRA) enforces stringent guidelines for therapeutic claims, translators have to adapt strategies to meet the requirements, which inevitably leads to variations in how TCM terms are rendered.

Legal constraints from the authority

In the *Drug Registration Guidance Document (DRGD)* by the NPRA Malaysia (hereinafter referred to as the Authority) and under the *Control of Drugs and Cosmetics Regulations (CDCR) 1984*, Regulation 2, ‘Product’ means (a) a drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose; or (b) a drug to be used as an ingredient of a preparation for a medicinal purpose. In this study, the sample products refer to herbal products under the category of Natural Products, excluding those made from animal organs or minerals (NPRA, 2023). Nevertheless, whether a product is accepted or rejected by the Authority depends largely on a number of factors, such as naming and appropriate translation of indications.

According to the NPRA regulations through its *Drug Registration Guidance Document* (2023), 17 conditions (see Supplementary File S1, Appendix 17, for the full list of 17 prohibited product-name conditions) are listed where product names are not allowed. To identify regulatory constraints most relevant to the translation of TCM

product names, we conducted a systematic content analysis. Among these, the second and seventh conditions were identified as having the most direct impact on translation decisions, as they conflict with TCM formulations featuring multiple ingredients and holistic claims.

According to Requirement 2 in the *Drug Registration Guidance Document*, the NPRA (2023) stipulates that ‘use of a single active ingredient as a product name in products containing more than one active ingredient is prohibited unless modifiers like “Plus”, “Compound”, or “Complex” are included’ (p. 1). Thus, a product containing both tongkat ali and ginseng cannot be named Tongkat Ali Capsule but must instead adopt a name like Tongkat Ali Complex Capsule. This regulation directly conflicts with one of TCM’s traditional naming principles, where multi-ingredient formulations are often named by their primary herb to reflect their holistic therapeutic effect (National Food and Drug Administration, 2017). For example, Fang Feng Decoction (documented in *Xuanming Lunfang*¹) consists of 12 herbs including Fang Feng (Radix Saposhnikoviae), as documented in *Shen Nong Ben Cao Jing (Shen Nong’s Herbal)*², and is named after the main herb Fang Feng. Translators must therefore balance a tension between literal translation of TCM names (e.g. Tongkat Ali) and regulatory compliance, which demands explicit labelling of multi-ingredient formulations (e.g. Tongkat Ali Complex Capsule). Failure to adapt risks misleading consumers and regulatory rejection.

Under Requirement 7 in the *Drug Registration Guidance Document*, the NPRA (2023) further prohibits the ‘use of product names incoherent with the approved indication’, particularly when a name highlights a single indication despite multiple approved indications (p. 2). For example, a product named Cough Syrup would violate this rule if its approved indications include cough, dizziness, flu, and itch. This poses a significant challenge for TCM, where products traditionally make holistic claims (Zhuang & Zhang, 2001), such as 行气化湿 (*xingqi huashi*, circulate qi and transform dampness) (Pharmacopoeia of the People’s Republic of China, 2020; World Health Organisation, 2022). According to the NPRA guidelines, such claims must be simplified to ‘low-level’ indications like ‘supports digestion’ (p. 31), omitting culturally specific concepts like dampness (湿气, *shiqi*), a TCM syndrome associated with metabolic stagnation or fluid imbalance. Translators are thus compelled to prioritise regulatory compliance over conceptual fidelity, which often results in reduced semantic richness and a disconnection from TCM’s theoretical framework.

As for indications, the registered product shall only be indicated for use as approved by the Authority. Indications other than those specified and accepted at the time of registration must not be included in any product literature, data sheets, package inserts, labels, etc., without the prior permission of the Authority. Additionally, ‘only low-level claim(s) will be accepted’ for traditional medicines (p. 31), which means that the NPRA permits only modest or limited therapeutic claims, known as ‘low-level claims’ on product packaging. These claims must align precisely with the specific indications that have been officially approved for the product. These legal specifications directly impact what may or may not be translated.

Translation as a purposeful activity

Translation is a purposeful activity (Nord, 1997). This activity is considered intentional, interpersonal, and cross-cultural when the target text is intended to achieve a purpose

and address an audience different from the intended readership of the original (Song, 2020). The translation of TCM packaging serves at least two purposes: ensuring legal compliance for product registration in the target culture and appealing to potential customers (Cheng & Glynn, 2022). Shi (2017) further identifies three major purposes of TCM product name translation: disseminating TCM knowledge within the global pharmaceutical industry, promoting TCM culture, and facilitating the international marketing of these products. Translators should pay attention to these purposes when translating TCM terms to ensure that translations align with the cultural and cognitive expectations of target readers (Pan & Zhang, 2019).

While Skopos theory emphasises the function of the target text, practical constraints, such as restricted packaging space, require translators to prioritise communicative purposes (Huang & Zhao, 2021). For example, legal compliance (the primary skopos, or communicative purpose) may take precedence over readability enhancements (secondary skopos) or multilingual labelling (tertiary skopos). In such cases, translators may replace therapeutic claims with legally acceptable, low-profile expressions, such as ‘maintain health’ instead of ‘treat’, to comply with regulations while preserving communicative clarity (NPRA, 2023a). This issue is particularly pronounced in the Malaysian market, where some products have indications translated into both English and Malay to target multilingual consumers. For example, the TCM product *Active Liva Capsules* has indications in Chinese, ‘传统上用于养护肝脏’, in English, ‘Traditionally used as a liver tonic’, and in Malay ‘Digunakan secara tradisional sebagai tonik hati’ (Figure 1). This

Active Liva Capsules	Active Liva Capsules
<p>牛樟芝，台湾特有的真菌，生长于台湾本土特有的牛樟树干心材的内壁，生长十分缓慢，亦不易栽培，使得牛樟芝产量稀少。</p> <p>牛樟芝经过科技培养，采收及冷冻干燥，制成这养生保健的珍品。</p> <p>主治：传统上用于养护肝脏。</p> <p>服用方式：成人每日两次，每次一粒，宜于早晚餐前服用。</p> <p>保存方式：放置于30°C以下干燥处及避光保存。食用后请关紧瓶盖。</p> <p>妊娠及哺乳期：无足够的安全数据。</p> <p>Indikasi: Digunakan secara tradisional sebagai tonik hati. Cadangan Dosej: Dewasa - 1 biji setiap kali, 2 kali sehari, sebelum sarapan dan makan malam. Cara Penyimpanan: Simpan di tempat yang kering di bawah 30°C. Lindungi daripada cahaya dan kelembapan. Tutup penutup dengan ketat selepas makan. Penghamilan dan penyusuan: Tiada data berkenaan.</p> <p>Ramuan/成分/Ingredients:</p> <p>Setiap 500mg mengandungi / 每一份量500毫克含/ Each 500mg capsule contains the following ingredient:</p> <p>牛樟芝菌丝体 Antrodia Cinnamomea Mycelia Powder 500mg/毫克</p> <p><i>Ini adalah ubat tradisional. Sila merujuk kepada ahli farmasi/ doktor sebelum mengambil produk ini. Jauhkan daripada capaian kanak-kanak. 此乃传统草药。使用前，请咨询您的药剂师或医生。远离儿童可触及之处。 This is a traditional preparation. Please consult your pharmacist/doctor before taking this product. Keep out of reach of children.</i></p>	<p>Antrodia Cinnamomea is a fungus found only in Taiwan. It is a rarity as it grows slowly only in the inner trunk of local tree C.Kanehirai.</p> <p>The fungus are cultivated, harvested and freeze dried to make this health product.</p> <p>Indication: Traditionally used as liver tonic. Dosage: Adult - 1 capsule each time, twice a day before breakfast and dinner. Storage: Keep in a dry place below 30°C. Protect from light and moisture. Close cap tightly after use. Pregnancy and Breastfeeding: Insufficient reliable data.</p> <p>Product Owner: Chang Gung Biotechnology Co., Ltd. 8F, No. 201-30, Tunghwa N. Road, Songshan District, Taipei City 105, Taiwan.</p> <p>Diimport oleh / Imported by Product Registration Holder: Eu Yan Sang (1959) Sdn. Bhd. 195901000194 (3544-P) No. L2-01 & L2-02, 2nd Floor, Shaw Parade, No. 152, Changkat Thambi Dollah, 55100 Kuala Lumpur, Malaysia. Customer Careline: 1 300 888 213</p> <p>Dikilangkan oleh/ Manufactured by: Long Shine Biopharma Co., Ltd. Building A, No. 115-1, Xiabu, Xiaying VII., Jiali Dist., Tainan City 72270, Taiwan.</p>

Figure 1. TCM Active Liva Capsules.

example illustrates the practical tensions between multilingual presentation, legal compliance, and conceptual fidelity that translators must manage.

To address these challenges, translators must balance preserving the cultural and conceptual characteristics of TCM terms with prioritising readability for the intended audience. These approaches are not mutually exclusive. Rather than choosing strictly between source-oriented fidelity or target-oriented adaptation, translators can apply a flexible approach. For example, a source-oriented strategy that preserves the cultural and conceptual essence of TCM terms ensures authenticity in representing traditional knowledge. Skopos theory complements this at a macro-level by providing a functional perspective through which translators can selectively adapt translation strategies to meet different needs. This aligns with Vinay and Darbelnet's (1958/1995) model, which, at the micro-level, provides concrete procedures such as borrowing, calque, and modulation for operationalising these strategies.

Translation procedures by vinay and darbelnet

Although originally developed for French-English language pairs, Vinay and Darbelnet's (1958/1995) typology of translation procedures remains a valuable analytical tool for examining micro-level strategies in translation studies. Scholars continue to recognise the importance of Vinay and Darbelnet's taxonomy. Hatim and Munday (2004) remark that 'Vinay and Darbelnet's detailed taxonomy has influenced many theorists' (p. 33), and Schjoldager et al. (2008) emphasise its pedagogical value for concrete translation analysis. More recently, Munday, Ramos Pinto, and Blakesley (2022) still describe it as 'one of the best-known and most representative models' in the field (p. 73). Empirical Chinese-into-English studies further confirm its contemporary relevance. Chen (2013) demonstrates how the seven procedures explain shifts when translating Chinese empty words. In a different regulatory context, Cheng and Glynn (2022) apply Vinay and Darbelnet's model to translation of TCM products sold in the United States. Amenador and Wang (2022) use the taxonomy, alongside other frameworks, to examine the translation of 4,000 Chinese dish names containing culture-specific items. Building on this body of works, this study adopts the model descriptively to analyse the translation of names and indications of TCM products under Malaysia's NPRA regulations. The main approaches are direct (or literal) and oblique translations (Figure 2).

As the name suggests, direct translation involves a literal rendering that considers the lexical equivalence between the source and target texts. Vinay and Darbelnet (1958/1995) highlight that, despite linguistic and metalinguistic structural similarities between two languages, challenges persist, creating a gap in intercultural communication. Therefore, it is essential to employ appropriate strategies and procedures under direct translation. These strategies are borrowing, calque, and literal translation. Borrowing involves integrating words or expressions from the source language into the target language without translation and is believed to be 'the simplest' of all translation methods (p. 31). This approach can be seen in English translation of TCM term 气 *qi*. Rather than translating it as 'energy' or 'air', which would oversimplify or distort its cultural and philosophical meaning, translators often retain '*qi*' to preserve the conceptual integrity of TCM theories. Calque is a special kind of borrowing whereby a language borrows a word or phrase from another language through literal translation, maintaining the

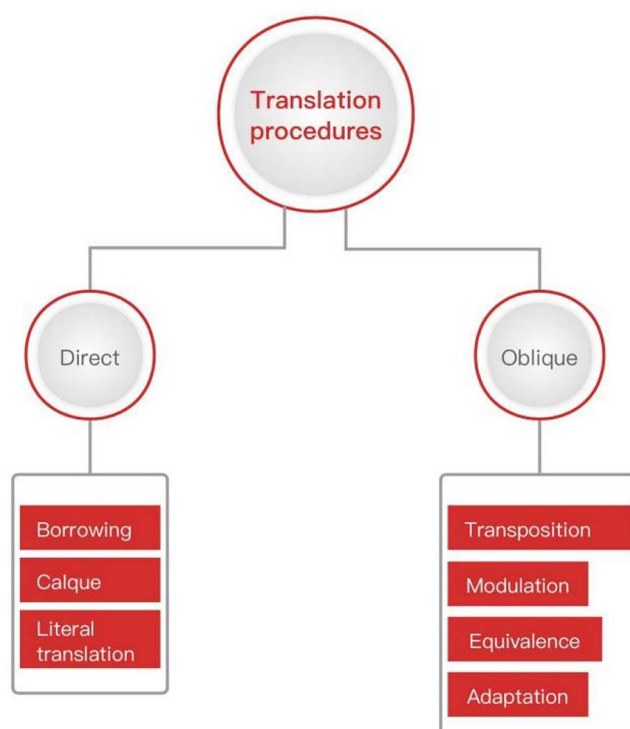


Figure 2. Vinay and Darbelnet's translation procedures.

structure and form of the original expression (p. 32). In TCM translation, an example of calque is the rendering of 经络系统 *jingluo xitong* as 'meridian system.' Instead of borrowing the term *jingluo* directly, *jing* (channel) and *luo* (network) are collectively translated as 'meridian', while *xitong* is translated as 'system.' Literal translation encompasses the translation of the source language text 'word-for-word' into the target language (pp. 33–34), such as translating 滋肾养肝 *zishen yanggan* in Chinese to 'enrich the kidney and nourish the liver' in English.

According to Vinay and Darbelnet (1958/1995), if translators find a literal translation to be unacceptable after attempting direct procedures, they should resort to oblique translation methods: transposition (replacing one word class with another without changing the meaning of the message), modulation (a variation of the form of the message obtained by a change in point of view), equivalence (rendering the same situation by two texts using completely different stylistic and structural methods), and adaptation (used when a situation in the source message is unknown in the target culture, requiring creation of a new, equivalent situation) (Vinay & Darbelnet, 1958/1995, pp. 36–39).

Transposition involves 'replacing one word class with another' while preserving the same meaning (p. 36). This is illustrated by the TCM term on diagnosis 辨证论治 *bianzheng lunzhi* translated as 'treatment based on pattern identification' where the verb-noun structure ('identify pattern') is transposed into a noun phrase ('pattern identification') in English. Modulation is defined as a variation of the form of the message, obtained by changing the point of view, particularly when a literal or transposed translation would be

grammatically correct but awkward or unsuitable in the target language (p. 36). In TCM translation, the phrase 安神 *anshen* is translated by the WHO as ‘calm the mind’. While a literal translation—‘calm the spirit’—would be grammatically acceptable, it risks sounding mystical to English-speaking readers. The translation shifts the focus toward ‘mind’ to emphasise emotional and psychological well-being and improves naturalness and clarity in the target language. Equivalence aims to find similar meaning in the target language for a source language expression, even if the form differs, as with the Chinese idiom 心肾不交 *xinshen bujiao*, which is translated into English as ‘disharmony between the heart and kidney energies’. In Vinay and Darbelnet’s words, ‘one and the same situation can be rendered by two texts using completely different stylistic and structural methods’ and such equivalence is mostly found in the translation of idioms and proverbs (p. 38). With adaptation, we reach ‘the extreme limit of translation’: it is used in cases where cultural references or elements in the SL message are ‘unknown’ in the TL culture (p. 39). In such cases, translators have to create a new situation that can be considered as being equivalent, as seen in the TCM term 上火 *shangshuo*, which is rendered as ‘heatiness’ or ‘internal heat’ in English to enhance understanding among English-speaking readers.

Vinay and Darbelnet’s classic taxonomy continues to exert most influence today and has been instrumental in highlighting a wide range of translation techniques (Munday et al., 2022). By categorising techniques such as borrowing, adaptation, and calque, Vinay and Darbelnet’s model supports a precise, systematic analysis that reveals how translators strategically balance delivering medical information accurately with meeting regulatory requirements in contexts like TCM packaging translation in Malaysia.

Materials and methods

Data were collected from the websites of the two companies (see Table 1) Eu Yan Sang 余仁生 (Figure 3) and Sung Khong 顺康 (Figure 4), selected from an initial pool of five TCM pharmaceutical companies registered in Malaysia (Hai-O海鷗, Lo Hang Ka老行家, Herbal Farmer藥材農夫, Eu Yan Sang 余仁生 and Sung Khong 顺康). The other three companies were excluded because their product offerings (primarily health supplements, gifts or non-therapeutic herbs) did not align with the definition of TCM products described in section two of DRGD (2023), which focuses on medicinal items with explicit therapeutic claims. Thus, the final sample represents all identified TCM products sold by these two companies that fit the defined inclusion criteria at the time of data collection.

Eu Yan Sang, a multinational company with 144 years of history, was selected due to its dominance in urban markets (e.g. Kuala Lumpur) and e-commerce platforms (Eu Yan Sang, n.d.). The company specialises in Chinese Proprietary Medicines (CPMs), which are defined as ‘medicinal products, used according to the traditional Chinese medicine

Table 1. Profile of the traditional Chinese medicine (TCM) companies.

Company Name	History	Location	Product Category	URL
Eu Yan Sang 余仁生	144 years	Malaysia	Health Supplement, Herbs, Pills & Powders, Health Food, ...	https://www.euyansang.com.my/en_MY/home
Sung Khong 顺康	Founded in 1988	Malaysia	Herbal Soup, Crude drug/Herbs, Precious Herbs, ...	https://www.sungkhong.com.my/



Figure 3. One of the outlets of EU Yan Sang in Kuala Lumpur.

(TCM) system of treatment that have been manufactured into finished dosage forms (e.g. tablets, capsules or pills)'(Li et al., 2013). As a leading supplier of NPRA-registered CPMs, Eu Yan Sang's products strictly adhere to Malaysia's regulatory requirements for therapeutic claims.

Sung Khong, founded in 1988, was included based on its product portfolio, which primarily comprises traditional formulations with a smaller number of products registered under the CPM category (Sung Khong, n.d.). Its inclusion enables the study to cover a broader range of TCM products marketed in Malaysia, including both traditionally formulated and officially regulated items.



Figure 4. One of the outlets of Sung Khong in Ipoh.

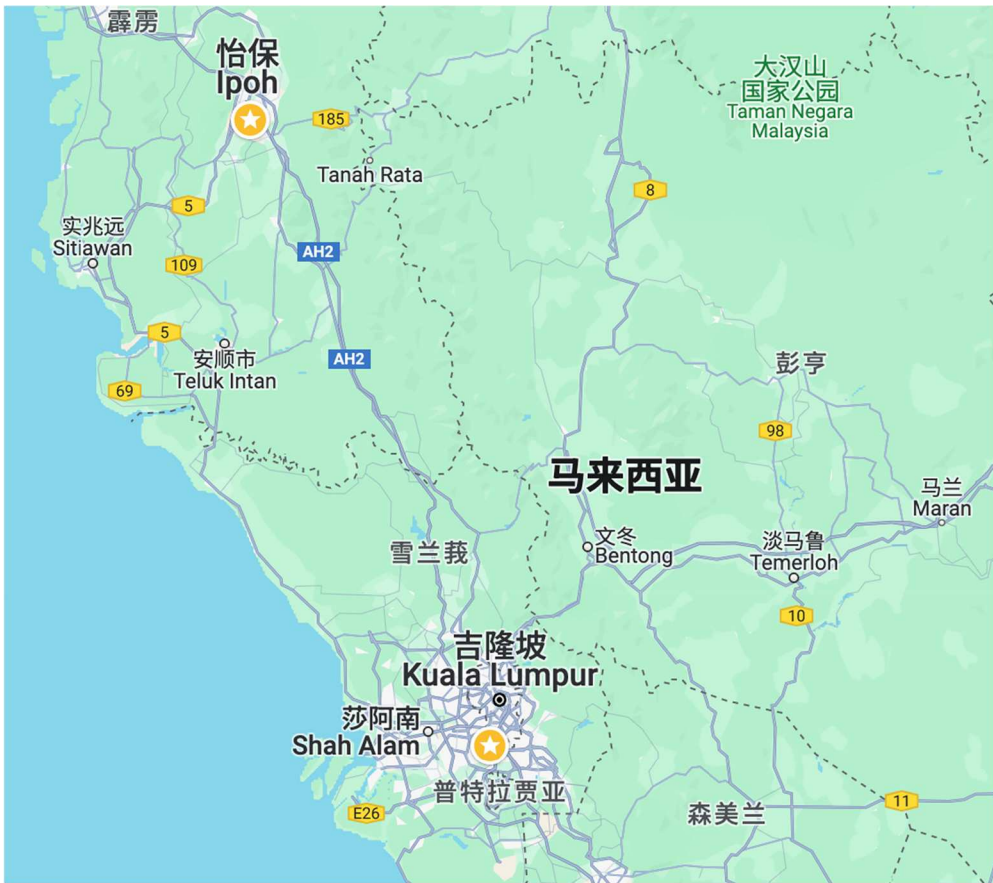


Figure 5. Geographical location of the data sourcing stores.

From these two companies, which are recognised players in Malaysia's TCM sector, 36 sample products³ (e.g. capsules, pills, powders) were collected via their publicly accessible websites. Product availability and labelling consistency were cross-verified through store visits in Kuala Lumpur and Ipoh, where both companies maintain a retail presence (Figure 5). To focus on items subject to NPRA's scrutiny, products categorised as gifts, health supplements, or non-medical herbs, or brands deviating from the CPM definition, were excluded. The sample size aligns with qualitative research standards for in-depth textual analysis, prioritising depth over breadth (Creswell & Poth, 2018), while the company selection offers insight into regulatory and linguistic issues relevant to widely marketed TCM products.

Data extraction involves three main steps. Initially, packaging images were stored in a Microsoft Word file. Subsequently, optical character recognition (OCR), a function embedded in Tencent WeChat, was employed for text recognition. Finally, bilingual data of product names and indications was stored in a Microsoft Excel file for TT and ST comparison. To ensure research reliability, examples used for translation comparison were reviewed by a TCM expert. The terminology outlined in the WHO international standard for traditional Chinese medicine (2022) and the *Pharmacopoeia of the People's*

Republic of China (2020) was followed where applicable. In line with the source materials, original script forms (e.g. simplified Chinese, and/or traditional Chinese) were retained to reflect their linguistic, cultural, regional, and regulatory significance.

According to the *Law of the People's Republic of China on the Standard Spoken and Written Chinese Language* (National People's Congress, 2001), simplified Chinese is the standard script for official and public use (Chapter 1, Article 2). However, Article 27 of Chapter 2 permits the use of traditional characters in contexts such as publication, education, and research, particularly to preserve cultural heritage. This legal provision underpins the continued use of traditional Chinese in TCM scholarship—for instance, in classical works such as the *Huang Di Nei Jing* (《黄帝内经》 *Yellow Emperor's Inner Canon*) or *Shen Nong Ben Cao Jing* (《神农本草经》 *The Divine Farmer's Materia Medica*), where script fidelity supports textual authenticity and etymological precision (NPC, 2001).

As Wiseman (2023) notes, the language of Chinese medicine remains largely classical in style. Traditional characters are also maintained in regions such as Taiwan, Hong Kong, and Macau, as well as in diasporic Chinese communities in Southeast Asia, where the use of script may signal political or regional identity (Hong, 2018). Conversely, simplified characters dominate modern TCM publications and regulatory texts in mainland China, such as the *Pharmacopoeia of the People's Republic of China* (2020), which reflects broader standardisation efforts and greater accessibility.

In this study, we intentionally retain both simplified and traditional Chinese characters when presenting product names and indications. This approach honors the textual and cultural origins of TCM terminology while ensuring fidelity to official documentation. Importantly, the concepts remain equivalent and mutually intelligible regardless of script variation (e.g. 气/氣 for *Qi*) to ensure consistency across regions (World Health Organisation, 2022).

Results

The subsequent sections offer a thorough examination of the translation of TCM names and indications. As is the focus of this study, each section will centre on the legal requirements and corresponding constraints over translation. As can be noticed, there is a mixed use of simplified and traditional Chinese characters in both product names and indications. Since these names and indications are proprietary to their respective owners, we have chosen to retain both forms to uphold the integrity of the original text.

TCM names

Concerning what names may or may not be allowed for registration, the Authority, through DRGD, listed 17 situations or rules where product names are not allowed for registration. After rounds of checking 36 product names against each rule, it was observed that most rules were well followed.

For instance, the medication 灵芝'破壁'孢子胶囊 is rendered as 'Ling Zhi "Cracked" Spores Capsules Plus'. Initial examination reveals that the term 'plus' is not evident in the source text. However, Rule 2 of Appendix 17 stipulates that 'Prohibited use of a single active ingredient as a product name in products containing more than one active ingredient, except if the "product name contains words such as Plus, Compound,

Complex, Herbanika”’. This regulation clarifies that although the English translation of 灵芝‘破壁’孢子胶囊 utilises a single active ingredient, it conforms to legal requirements as it includes the term ‘plus’. Among 36 samples, three (3) TCM products feature single ingredient in their English translations, with the other two being 止咳露 Bee Propolis-Plus Cough Nectar (Traditionally used for relieving cough and reducing phlegm) and 鹿尾耙丸 Lok Mei Pa Plus Pills (Traditionally used for men’s health and strengthening the waist and body) (Figure 6).

However, the translation of one specific product name and its indications appears to be confusing. According to Appendix 17, Rule 7 specifies that a name is not permitted if it ‘contains only one product claim, but the product has more than one approved indication’. For instance, the product 驅感冒發燒顆粒 is translated as Cold & Fever Relief Granules. The indications include 传统用于舒缓风热感冒、发烧、头痛、咳嗽、鼻咽干热和喉咙痛, translated as ‘Traditionally used to relieve common cold with fever, headache, coughing, dry mouth, and sore throat.’ Here, the product has multiple approved indications. However, in the English translation of the product name, ‘cold’ and ‘fever’ are presented in a coordinating relation, suggesting they are treated separately. In contrast, within the indications, it is phrased as ‘cold with fever’, where ‘fever’ functions as a modifier for ‘cold’. If the product name were translated as ‘cold with fever’, indicating a single product claim, it would violate the 7th rule. The use of the coordinating conjunction ‘and’ in the product name and the preposition ‘with’ in the indications manages to comply with the legal requirements of the Authority. In summary, the English translation of indications better reflects syndromes in this case. As for the remaining samples, the English translations of product names adhere to the legal requirements.

The English translation of product names is indispensable for the global dissemination of TCM. Analysis of the sample reveals that several options are feasible. The subsequent paragraphs present the methods and sample examples.

Borrowing. This method entails incorporating words or expressions from the source language into the target language without translation. Manufacturers of the sample products in this study vary, with those of Cantonese origin typically using non-standard romanisation based on Cantonese pronunciation (e.g. 蜜炼川贝枇杷膏, NIN JIOM PEI PA KOA), while modern products from mainland China utilise mandarian Hanyu pinyin (e.g. 莲花清瘟胶囊, LIANHUA QINGWEN JIAONANG, Figure 7). Older products may employ different romanisation systems, such as Wade-Giles or Yale (e.g. 六味地黄丸, Luk Mey Pills). Transcription, or transliteration, as discussed by Glynn (2021), is considered



Figure 6. Product names containing ‘Plus’.

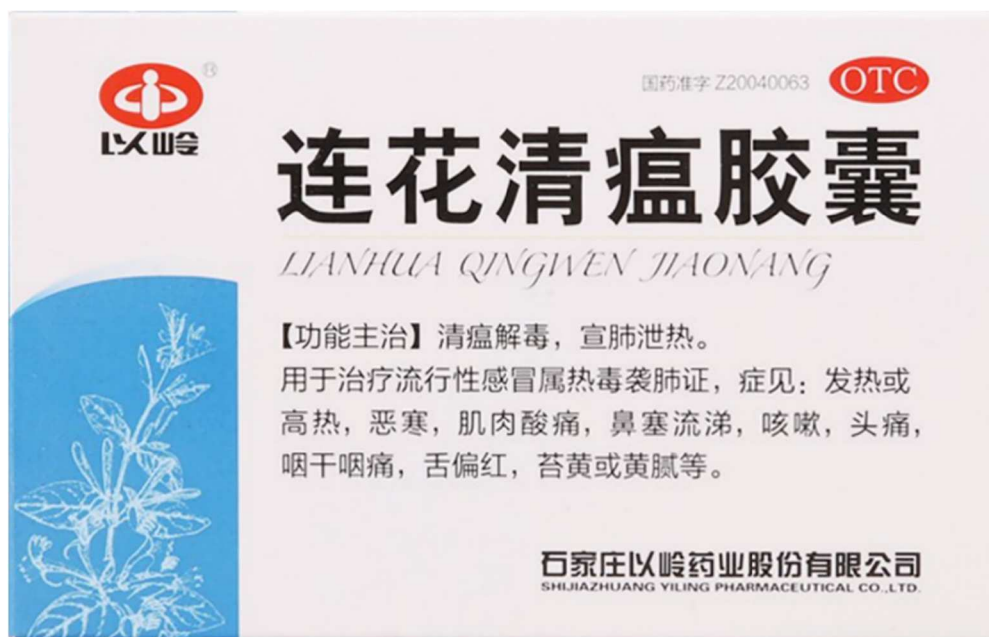


Figure 7. TCM Lianhua Qingwen Jiaonang.

a form of borrowing in translation, a concept also supported by Vinay and Darbelnet (1958/1995). Given the unique conceptual terms in Chinese medicine, translators often resort to transcription or transliteration (Guang, 2009). As no precise translation can achieve the actual meaning by using pinyin (WFCMS, 2008), the use of Latinised pinyin is advocated as a standard practice to fully reflect the unique cultural characteristics of Chinese medicine (Zou, 2015). Sample examples include 白凤丸 (BAI FENG WAN), 补气健中丸 (Bu Qi Jian Zhong Pills), and 杞菊地黄丸 (Qi Ju Di Huang Pills). Notably, 50% of the translated product names in the samples employ borrowing as a translation method.

Literal translation. This approach involves translating the source language text word-for-word into the target language. As Vinay and Darbelnet (1958/1995) point out, 'the translator's task is limited to observing the adherence to the linguistic servitudes of the TL' (p. 33). Similarly, Hatim and Munday (2004) observe that 'literal translation can work admirably in a range of contexts and for a variety of texts', and that 'the bulk of what we do as translators requires little more than literal translation' (p. 253). For instance, 珍珠末, a product traditionally used for relieving heat (Figure 8), is translated as 'Pearl Powder'.

Adaptation. This strategy involves adjusting cultural references in translations to enhance their intelligibility or acceptability in the target culture. For example, the product 顽固寒咳药粉, traditionally used for cold and cough relief and to reduce phlegm, could be rendered as 'Stubborn Cold Cough Powder' or 'Persistent Cold Cough Powder', but is translated as 'Cold Cough Powder', omitting 'Stubborn/Persistent' for clarity and simplicity. Similar adaptations are made for other TCM products, such as 顽固热咳药粉 'Hot Cough Powder', 轻微热咳药粉 'Mild Hot Cough Powder', and 轻微寒咳药粉 'Mild Cold Cough Powder'. In the third and fourth product, the word 'mild' is added to differentiate and indicate severity of the syndrome. This aligns with Appendix 17, which



Figure 8. TCM珍珠末Pear Powder.

prohibits confusion (Rule 4) (p. 1) and restricts similarity to existing names (Rule 9) (p. 2). These adaptations demonstrate how translation strategies are not merely linguistic adjustments but deliberate responses to regulatory constraints on product labelling.

Borrowing and modulation. Modulation involves changing perspective or rephrasing while retaining the same meaning. Relying solely on borrowing, particularly excessive use of pinyin, may not ensure comprehensibility for the target readers. For example, 喉宁化痰散 (Hou Ning Phlegm Relief Powder) integrates pinyin with a functional claim, thereby enhancing immediate comprehension for target readers (see Figure 9). This modulation is necessary, as relying solely on pinyin may not convey meaning to those unfamiliar with Chinese. For example, 抗毒清肺丸 is rendered as 'Kang Du Qing Fei Pills'. Without consulting the indications, a consumer cannot discern the function of the medicine solely from its name. The combination of borrowing and modulation methods can offset the limitations of a single method. Table 2 presents methods used to translate the TCM names under the procedures by Vinay and Darbelnet.

The direct approach to translation involves two strategies: borrowing and literal translation. Borrowing, utilised in 50% of cases, involves directly transcribing Chinese pinyin into English to preserve the Chinese characteristics. While this may not be immediately understandable to consumers, borrowing or transliteration is typically used for TCM terms that have no corresponding concepts in English (Lim et al., 2022). Literal translation, employed in 25% of cases, translates words and phrases exactly as they appear in the packaging. Effective literal translation allows target readers to identify the active ingredients of TCMs. For instance, the product 冬虫夏草 'Capsules Of Cordyceps Sinensis Mycelia' directly reflects its main ingredient (Figure 10). However, calque can lead to confusing translations, as seen with '冬虫夏草' if literally translated as 'winter worm summer



Figure 9. TCM喉宁化痰散Hou Ning Phlegm Relief Powder.

herb', despite *Cordyceps sinensis* being a fungus and algae organism rather than a grass or insect.

The oblique approach represents a more flexible translation strategy. It features the procedure of adaptation, which is applied in 17% of translations. Adaptation allows for significant alterations to the original text to suit not only the cultural and functional context of the target language but also the legal requirements governing product labeling in the Malaysian context. This approach may include changes in the form, content, and style of the source language to make the product name more comprehensible or appropriate for the target audience.

Lastly, the mix mode approach combines elements of the two aforementioned strategies. It involves borrowing and modulation and accounts for 8% of translations. This mixed method starts with borrowing elements from the source language and then modulates them to better fit the multi-lingual and multi-cultural context of the target society. This mixed method offers the advantage of facilitating comprehension while preserving authenticity. Nevertheless, the main drawback of this technique is its greater demand for space.

Table 2. Methods for translating TCM product names.

Translation Approach	Methods	Percentage
Direct	Borrowing	50%
	Literal translation	25%
Oblique	Adaptation	17%
Mix mode	Borrowing and modulation	8%



Figure 10. TCM冬虫夏草Capsules of Cordyceps Sinensis Mycelia.

Indications

Indications, or functional claims, play a crucial role in the packaging of TCM products and are a primary determinant for drug selection by consumers (Lin & Zhou, 2012; Quan et al., 2021). The accurate translation of these indications is paramount for the global acceptance of and customer trust in TCMs. Lin and Zhou (2012) note that TCM indications typically employ four-character structures in Chinese, such as 清热解毒 (clear heat and remove toxin), 理气健脾 (regulate qi and strengthen the spleen), and 活血调经 (circulate blood and regulate menstruation) (World Health Organization, 2022). Such structures are concise, neat, and rich in the culture and philosophy of traditional Chinese medicine. Translating these statements necessitates extensive medical knowledge to ensure readability for both medical professionals and patients (Liu et al., 2017). For instance, Y.T. Wang, an Associate Professor and PhD of traditional Chinese medicine, suggests rendering 清热解毒, 理气健脾, and 活血调经 as ‘clear heat and resolve toxin’, ‘rectify qi and fortify the spleen’, and ‘invigorate blood and regulate menstruation’ respectively (personal communication, 12 December 2023).

Legal restrictions on indication statements are evident in Malaysian jurisdictions. Malaysia’s National Pharmaceutical Regulatory Agency (NPRA) specifies acceptance only of ‘low-level claims’ for traditional medicines (NPRA, 2023b, p. 31). In this sample, TCM indications are categorised into seven groups, including areas such as general health maintenance, pain relief, and women’s and men’s health. For each category, the DRGD

stipulates that indications should adhere to the format 'Traditionally used ... / Digunakan secara tradisional ...' followed by a phrase indicating the intended purpose. For example, the TCM 鹿尾鞭丸 Lok Mei Pa Plus Pills has the following indication in Chinese: '传统用于维持男性健康，壮腰及增强体力'. The indication is translated as 'Traditionally used for men's health and strengthening the waist and body'. As for the source text, Y.T. Wang suggested 壮腰及增强体力 could be more concisely expressed as '强腰健体' (personal communication, 12 December 2023).

All the TCMs in the sample are Chinese proprietary medicines. The indications are translated following structural patterns such as: 'Traditionally used for + -ing/noun', 'Traditionally used as + noun', or 'Traditionally used to + verb'. Following these structural patterns, most verbs in the sample Chinese indications are nominalised in their English translations. For example, 传统用于缓解喉咙痛 is translated as 'Traditionally used for symptomatic relief of sore throat'. This exemplifies the transposition method in Vinay and Darbelnet's (1958/1995) model, which involves 'replacing one word class with another' while preserving the original meaning (p. 36). The most common methods for translating indications are literal translation and calque, although calque can be somewhat awkward. For instance, the indication of the TCM 六味地黄丸 Luk Mey Pills/Liu Wei Di Huang Pills (Figure 11) reads in Chinese: '神倦无力，夜流盗汗，小便频数，阴虚体弱'. It is rendered as 'Traditionally used for fatigue, sweating at night, frequent urination and general weakness'. The rendition of 'general weakness' is close to the source text

六味地黄丸 Liu Wei Di Huang Pills

Composition per 12 grams dose:
 每 12 克剂量之成份

成份	克 / g
熟地黄 Radix Rehmanniae preparata	3.072
山药 Rhizoma Dioscorea opposita	1.536
山茱萸 Fructus Cornus officinalis	1.536
牡丹皮 Cortex Moutan radidis	1.152
茯苓 Sclerotium Poria cocos	1.152
泽泻 Rhizoma Alisma orientalis	1.152
蜜糖 Mel	2.400

主治 : 传统用于神倦无力，夜流盗汗，小便频数，阴虚体弱。
 Indications : Traditionally used for fatigue, sweating at night, frequent urination and general weakness.

服法 : 成人每日一次，每次一瓶 (12克服)，用暖开水送下。宜餐前服用。
 Directions : Adults - One pack (12g) once a day with lukewarm water. To be taken before meal.

This is a Traditional Medicine. Please consult your pharmacist/doctor before taking this product. Contraindicated in pregnant women, Breastfeeding; Insufficient reliable data. Store below 30°C. Protect from light and moisture. Keep out of reach of children. Jauhkan daripada capaian kanak-kanak.

此丸乃传统药品。服用本品前，请咨询您的药剂师或医生。孕妇忌食。哺乳期：无足够的安全数据。置于30°C以下干燥之处及避光保存。远离儿童可触及之处。

净重 Net Wt: 12g x 6 packs
 注册号码 Reg. No.: MAL 19973107T
 批号 / 制造日期 / 有效日期 Batch No. / Mfg. / Exp.

分销商 / Distributed by:
 Eu Yan Sang (1959) Sdn. Bhd. 195901000194 (254679)
 No. L2-01 & L2-02, 2nd Floor, Shaw Parade,
 JNo. 152, Changkat Thambi Dollah,
 55100 Kuala Lumpur, Malaysia.
 Customer Careline: 1 300 888 213

Eu Yan Sang (Singapore) Pte. Ltd.
 (Company Reg. No. 195500108C)
 Eu Yan Sang Centre, 21 Tai Seng Drive,
 Singapore 535223.

生产厂家 / Manufactured by Product Registration Holder:
 Weng Li Sdn Bhd 198001000094 (53874-07)
 (Member of Eu Yan Sang Group of Companies)
 2 & 4, Perstarian 1/118C,
 Desa Tun Razak Industrial Park II,
 56000 Kuala Lumpur, Malaysia.

9 557647 315154

Figure 11. TCM六味地黄丸Luk Mey Pills/Liu Wei Di Huang Pills.

主治：传统用以强身健体，治疗体质虚弱、痛经、月经失调及产后失调。

剂量

成人：宜餐前服用。
 强身健体：每星期服食1瓶。
 治疗体质虚弱：每隔两日服食1瓶。
 痛经、治疗月经失调：每日服食1瓶。
 产后调补身体：须在恶露已清（大约产后10日左右）方开始服用，每日服食1瓶，连服数日。

此为传统药品。此产品含动物成分。服用前，请咨询您的药剂师或医生。

储存

置于30°C以下干燥处及避光保存。

禁忌

发烧、感冒及行经期间，应暂停服食。孕妇忌食。本品对于授乳者和儿童的效用尚未知晓。不可过量服用所建议之剂量。长期服用之安全性尚未知晓。远离儿童可触及之处。

每14克剂量之成分
 Composition per 14 grams dose:

白术	Rhizoma Atractylodes macrocephala	1115mg
川芎	Rhizoma Ligusticum chuansiong	391mg
泽兰	Herba Lycopus lucidus	416mg
麦冬	Radix Ophiopogon japonicus	272mg
菝葜	Rhizoma Curcuma aeruginosa	582mg
远志	Radix Polygala tenuifolia	555mg
茯苓	Sclerotium Folia cocos	603mg
艾叶	Folium Artemisia argyi	279mg
香附	Rhizoma Cyperus rotundus	580mg
砂仁	Fructus Amomum villosum	292mg
益母草	Herba Leonurus japonicus	391mg
苍术	Rhizoma Atractylodes lancea	771mg
当归	Radix Angelica sinensis	596mg
白芍	Radix Paeonia lactiflora	488mg
女贞子	Fructus Ligustrum lucidum	301mg
黄芩	Radix Scutellaria baicalensis	292mg
芪	Radix Astragalus membranaceus	1115mg
杜仲	Cortex Eucommia ulmoides	101mg
人参	Radix Panax ginseng	249mg
鹿茸	Cornu Cervi pantotrichum	249mg
亚麻子	Semen Linum usitatissimum	157mg
肉桂	Cortex Cinnamomum cassia	149mg
蜜糖	Mel	4056mg

Indications: Traditionally used for health and general weakness, relieve menstrual pain, regulating menstrual ailments and malnutrition after childbirth.

RECOMMENDED DOSAGE

For adults: To be taken before meal.
For health maintenance: 1 bottle of pills taken once weekly.
For general weakness: 1 bottle of pills taken at every 2 days interval.
For relieving menstrual pain and regulating menstrual ailments: 1 bottle of pills taken once daily.
For malnutrition after childbirth: 1 bottle of pills taken once daily, repeating for several days. It should be taken after clearing labour discharge (normally about 10 days).

This is a Traditional Medicine. This product contains animal part. Please consult your pharmacist/doctor before taking this product.

STORAGE

Store below 30°C. Protect from light and moisture.
 Avoid consumption when suffering from fever or influenza or during menstruation period. Contraindicated in pregnant women.
 Safe use in lactating women and children has not been established. Do not exceed the stated dose. Safety on long term use has not been established. Keep out of reach of children. Jauhkan daripada capaian kanak-kanak.

分銷商 Distributed by:
Eu Yan Sang (1959) Sdn. Bhd. 19801000194 (3544-P)
 No. L2-01 & L2-02, 2nd Floor, Shaw Parade,
 No. 152, Changkat Thambi Dollah, 55100 Kuala Lumpur, Malaysia.
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Eu Yan Sang (Singapore) Pte. Ltd. (Company Reg. No. 198801083)
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生产厂商 Manufactured by Product Registration Holder:
Weng Li Sdn. Bhd. 19802100020 (35874-G)
 (Member of Eu Yan Sang Group of Companies)
 2 & 4, Penjaran 1/118C, Desa Tun Razak Industrial Park II,
 56000 Kuala Lumpur, Malaysia.

MAL 11125061T

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 277103 10/23 09/26

Figure 12. TCM金牌白凤丸Gold Label Bak Foong Pills.

‘阴虚体弱’ but might have been more accurately rendered as ‘weakness due to Yin-deficiency (World Health Organisation, 2022)’. However, Y.T. Wang suggested that the source text ‘夜流盗汗’ should be replaced by ‘夜间盗汗’ or simply ‘盗汗’ (personal communication, 12 December 2023).

In general, the translation of indication is intelligible. One serious issue is that certain indications in Chinese ST contain terms not allowed by the Authority if translated literally. For instance, the TCM 金牌白凤丸Gold Label Bak Foong Pills (Figure 12) has the following indication in Chinese: ‘传统用以强身健体，治疗体质虚弱、痛经、月经失调及产后失调’，which can be literally translated as: ‘Traditionally used to strengthen the body and treat physical weakness, dysmenorrhea, menstrual disorders and postpartum disorders’. The problem for this translation is the use of ‘treat’, a term not allowed by the Authority. Conversely, the TT in the packaging has the word ‘treat’ omitted to meet the legal requirement from the Authority. Thus, the indication is ultimately rendered as: ‘Traditionally used for health and general weakness, relieve menstrual pain, regulating menstrual ailments and malnutrition after childbirth’. Grammatically, the indication ‘relieve menstrual pain’ could be improved as ‘relief of menstrual pain’ or ‘relieving menstrual pain’ to make the whole sentence a parallel structure. The translation has resulted in a modified indication emphasising health enhancement and symptom alleviation rather than therapeutic treatment. A

similar adjustment is made for the TCM product 保婴丹 (Bo Ying Compound) and 追風蘇合丸 (Zhui Feng So Hup Pills), wherein the term ‘治疗’ (treat) is replaced with terms like ‘relief’ or ‘improving’ to mitigate claims of therapeutic efficacy. By omitting treatment-related terms such as ‘treat’, ‘treatment’, and ‘cure’ and choosing terms such as ‘relief’, ‘improving’, and ‘preventing’, the translations showcase ‘low-level claims’ acceptable for DRGD (NPR, 2023b, p. 31). The translations adapt the content of the Chinese ST to the English TT and tone down the claims about the TCMS’ therapeutic benefits.

The method of omission is further exemplified in the translation of the TCM 理中丸 *Lei Zhong Pills*. The original indication, ‘对于因消化不良、打呕、腹泻及腰虚寒而致体质衰弱者非常有用’, can be literally rendered as: ‘It is very useful for those who are weakened by indigestion, vomiting, diarrhoea, and coldness in the lower back’. However, the official packaging translates it as: ‘Traditionally used for general weakness associated with indigestion, belching, mild diarrhoea, and stomach discomfort’. The adverb ‘very’ has been omitted. Additionally, the expression ‘mild diarrhoea and stomach discomfort’ deviates from the original meaning of ‘腹泻及腰虚寒’. According to DRGD regulations, a more accurate rendition could have been ‘Traditionally used for general weakness associated with indigestion, belching, diarrhoea, and waist cold’. Regarding the source text, Y.T. Wang suggests revising the ST to ‘消化不良，呕吐腹泻，下元虚寒者’ (personal communication, 12 December, 2023).

Bilingual packaging should not include unsupported health assertions in either the ST or TT. Indeed, the DRGD (2023) clearly states that ‘The registered product shall only be indicated for use as approved by the Authority, and indications other than those specified and accepted at the time of registration must not be included in any product literature, data sheets, package inserts, labels, etc. without the prior permission of the Authority’ (p. 39). Most TCM products in the sample have adhered to these regulations. To illustrate, indications stated in the Chinese text on the packaging of 京都念慈庵蜜炼川贝枇杷膏 *NIN JIOM PEI PA KOA*, a product sold in Malaysia, differ from those stated on the product sold in mainland China.

The product sold in China states that the TCM ‘润肺化痰、止咳平喘、护喉利咽、生津补气、调心降火。本品适用于伤风咳嗽、痰稠、痰多气喘、咽喉干痒及声音嘶哑’, which translates as ‘Nin Jiom Pei Pa Koa is formulated from Chinese herbal ingredients and plant extracts together with honey and sugar syrups and has a pleasant taste. It provides temporary relief of coughs and sore throat associated with common cold, influenza or similar ailments. Nin Jiom Pei Pa Koa is effective for the temporary relief of the symptoms of bronchial cough and loss of voice’. Obviously, much of the information related to function claims in Chinese ST is lost in the English TT (Figure 13). Nevertheless, the information regarding the packaging of the product in Malaysia is far more precise (Figure 14). The one sold in Malaysia states that the TCM ‘传统上用于缓解喉咙痛，咳嗽，化痰及清热’, which is rendered as: ‘Traditionally used for symptomatic relief of sore throat and cough, to reduce phlegm and body heatiness’. In the case of mainland China, most drug users rely on the Chinese ST for indications and are less likely to consult the English translation of indications, which makes it even harder for them to notice the discrepancy between the ST and TT.

Ideally, for Malaysian readers who may be less familiar with TCM concepts, translations would include explicitations and explanations to enhance clarity. However, since only an English translation is provided on the packaging and space is limited, such explicitations

京都念慈菴蜜煉川貝枇杷膏

【功能主治】

潤肺化痰、止咳平喘、護喉利咽、生津補氣、調心降火、本品適用於傷風咳嗽、痰稠、喉干痒及氣喘、咽啞、声音嘶哑。

請仔細閱讀說明書並按說明使用
或在藥師指導下購買和使用

NIN JIOM® PEI PA KOA

(Traditional Chinese Herbal Coughs Syrup)

Indications

Nin Jiom Pei Pa Koa is formulated from Chinese herbal ingredients and plant extracts together with honey and sugar syrups and has a pleasant taste. It provides temporary relief of coughs and sore throat associated with common cold, influenza or similar ailments. Nin Jiom Pei Pa Koa is effective for the temporary relief of the symptoms of bronchial cough and loss of voice.

Dosage

Adults : 3 times a day.
One tablespoon a time.
Children : 3 times a day.
Dosage to be reduced according to age.

Ingredients

Tendrilleaf Fritillary Bulb Loquat Leaf Fourleaf Ladybell Root Indian Bread Pummelo Peel Platycodon Root Prepared Pinellia Tuber Chinese Magnoliavine Fruit Snakegourd Seed	Common Coltsfoot Flower Thinleaf Milkwort Root Bitter Apricot Seed Fresh Ginger Licorice Root Almond Extract Menthol Honey Maltose Syrup
---	---

Figure 13. TCM NIN JIOM PEI PA KOA sold in mainland China.

京都念慈菴蜜煉川貝枇杷膏

【功能主治】
传统上用于缓解喉痛、咳嗽、化痰及清热。

【用法及用量】
成人 每日三次，每次一茶匙 (5ml)，空腹或饭后亦可服用；
小童 七至十二岁：每日三次，每次三份之二茶匙 (3.3ml)，
空腹或饭后亦可服用；
三至六岁：每日三次，每次三份之一茶匙 (1.7ml)，
空腹或饭后亦可服用。

将膏倒在茶匙中，然后放入口中，徐徐咽下，则药效更佳。
亦可以将膏加入温水，搅匀后服用。

【贮存条件】
贮存于30°C以下。避光及防潮。请将此药置于儿童不易触及之处。每次使用后，请把樽盖扭紧。

成份 KANDUNGAN / COMPOSITION:
Each 5 ml contains / Setiap 5 ml mengandungi :

川贝母	Bulbus Fritillaria Cirrhosa	60mg
枇杷叶	Folium Eriobotrya Japonica	14mg
南沙参	Radix Adenophora Tetraphylla	2mg
茯苓	Sclerotium Poria Cocos	2mg
化橘红	Exocarpium Citri Grandis	8mg
桔梗	Radix Platycodon Grandiflorum	5mg
法半夏	Rhizoma Pinelliae Preparata	2mg
五味子	Fructus Schisandra Chinensis	0.4mg
瓜蒌子	Semen Trichosanthes Kirilowii	2mg
款冬花	Flos Tussilago Farfara	8mg
远志	Radix Polygala Tenuifolia	8mg
杏仁	Semen Prunus Armeniaca	1mg
生姜	Rhizoma Zingiber Officinale	2mg
甘草	Radix Glycyrrhiza Glabra	55mg
薄荷脑	Mentholum	2mg
杏仁水	Aqua Armeniacae (Semen Prunus Armeniaca)	15mg
蜂蜜	Mel	271mg
糖浆	Syrup	5400mg

【注意事项】 请参阅说明书

NIN JIOM PEI PA KOA
This is a traditional medicine.
Thick, dark brown syrup with sweetish and almond odour.

INDICATIONS :
Traditionally used for symptomatic relief of sore throat and cough, to reduce phlegm and body heatiness.

DOSAGE / ADMINISTRATION :
Adult:
One teaspoonful (5ml) to be taken 3 times a day with or without meal.
Children :
Age 7-12 years: 2/3 teaspoonful (3.3ml) to be taken 3 times a day with or without meal.
Age 3-6 years: 1/3 teaspoonful (1.7ml) to be taken 3 times a day with or without meal.
Sip without water for better effect; or dissolve the syrup in warm water and drink slowly.

SIDE EFFECTS / CONTRAINDICATIONS :
Contraindicated in pregnant women.

WARNINGS / PRECAUTIONS :
This is a traditional medicine. Contraindicated in pregnant women. Insufficient reliable data in breastfeeding women. Please consult your pharmacist/ doctor if symptoms persist/ worsen. Shake well before use. Keep out of reach of children.

STORAGE CONDITIONS:
Store below 30°C. Protect from light and moisture. Keep the cap tightly closed after use.

PRODUCT REGISTRATION HOLDER /IMPORTED BY:
WENG SENG HENG MEDICAL HALL SDN. BHD.
219 & 221, LEBUH PANTAI 10300 PULAU PINANG, MALAYSIA

Figure 14. TCM NIN JIOM PEI PA KOA sold in Malaysia.

are not feasible. Ultimately, these translation differences arise from local regulations that prioritise clarity and accuracy, requiring translators to adapt to the constraints of limited packaging space.

In summary, most bilingual indications in both Chinese and English well adhere to the laws and regulations of the Authority of Malaysia. Overall, 28 out of 36 products employ the officially recommended indications. Although the Chinese indications of the other 8 products do not use the structure ‘传统用于’, their English translations use the phrase ‘Traditionally used for ...’ Despite the stylistic variations between the Chinese source text and the English target text, the translation of all 36 product indications manages to meet the official requirements.

Discussion and conclusion

This study has analysed the packaging of a sample of 36 TCMs available in Malaysia through an integrated analytical framework with Skopos theory at the macro-level and Vinay & Darblenet’s translation procedures at the micro-level. The results reveal how Malaysia’s regulatory framework, as enforced by the NPRA through the DRGD, shapes translation strategies that result in translation variations.

The study reveals strict compliance with the rules specified in Appendix 17 of the DRGD regulating the registration of product names. The analysis of sample products confirms that all of the products conform to the specified regulations. The application of multiple translation methods, including borrowing, literal translation, adaptation, and borrowing with modulation, highlights the flexibility and variety in translating TCM names. The prevalence of borrowing and literal translation, which accounts for 75% of the examples, suggests a balance between preserving the authenticity of Chinese culture (Li, 2010; Ye & Dong, 2017; Zou, 2015) and maintaining comprehension for the intended audience (Zhang & Dong, 2020). Appropriate translation of product names plays a vital role in expanding the market access of traditional Chinese medicine (TCM).

The translation of TCM indications closely corresponds to the regulatory requirements. The NPRA emphasises the acceptance of ‘low-level claims’ and underscores the need to align indications with approved ones. Translation methods such as transposition, literal translation, calque, and adaptation are employed to convey health claims within legal constraints. The impact of authority in shaping translation strategies is evident when terms such as ‘treat’ and ‘very’ in indication statements are either omitted or adapted to conform with NPRA’s suggested alternatives such as ‘relieve’ or ‘improve’. As a target-related strategy, adaptation is used by professional translators to adjust the translated text for a specific purpose. This adjustment is in keeping with the principles of Skopos theory, where the translation’s purpose determines the process and guides translators’ strategies (Dimitriu, 2004). Accurate translation of TCM indications or functional claims assists users in safely selecting appropriate medications.

The findings reveal a persistent tension between preserving TCM concepts, conforming NPRA regulations, and ensuring customer readability. Guided by Skopos theory (legal compliance first) and Vinay and Darblenet’s procedures, we propose a three-step decision path (Figure 15): where NPRA-mandated names and indications exist, translators should adopt those allowed terms (adaptation); where no mandate applies but the term is safety-critical, they may retain Pinyin and add a brief English gloss (borrowing plus

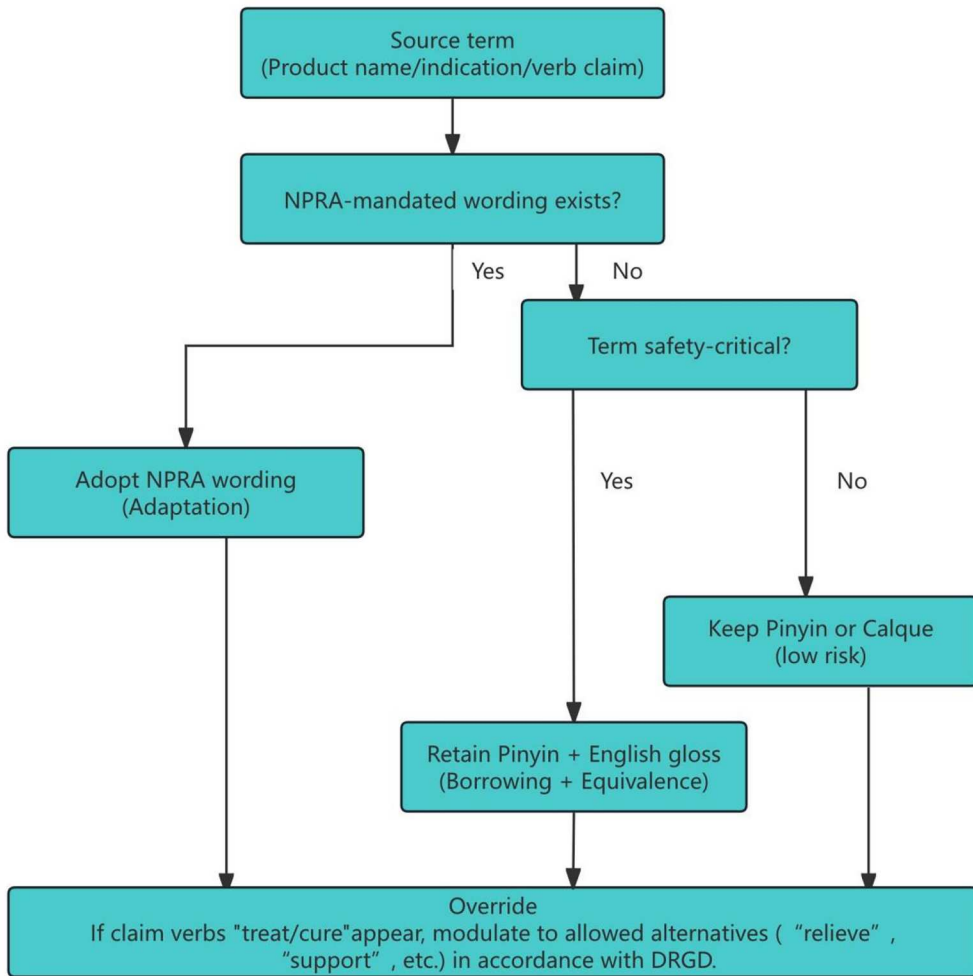


Figure 15. Three-step decision path for translating TCM product names and indications under Malaysia's NPRA regulations.

equivalence); and for low-risk cultural-flavour items, they may simply keep the Pinyin or employ a calque. Whenever the NPRA prohibits strong claims such as 'treat' or 'cure', those verbs must be modulated to allowed alternatives like 'relieve' or 'support.' Taken together, this hierarchy balances conceptual fidelity with legal compliance and consumer readability.

Appropriate bilingual translations of TCM product names and their indications play a key role in the selection and purchase of these medicines by overseas consumers (Jiang, 2002). Methods of borrowing, literal translation, transposition, adaptation, the mix mode of borrowing and modulation under Vinay and Darbelnet's translation procedures, and the method of omission are applicable in the translation of TCM packaging information under legal restrictions. These methods function individually or collectively and equip translators with a versatile toolkit to address challenges in translating TCM product names and indications.

Several TCMS may not fully adhere to NPRA requirements. The main reason is probably the enforcement of the regulations. While the Chinese source text may not comply with laws, English translations are adapted to meet regulatory requirements. The instances of non-compliance underscore the urgency of quality assessment within the regulatory framework of the authorities. A more robust approach to quality assessment could pave the way for the establishment of translation standards and guidelines for product names and indications. Standardisation would not only benefit consumers by facilitating easier comparison of TCM products in Malaysia but also empower producers to implement effective quality control measures.

Concerning the wording of some of the indications in the ST, a TCM expert has suggested improvements. The suggested versions keep the Chinese statement of indications updated. As researchers, we have observed translation ethics and respected the ST (Chesterman, 1997). However, we advocate for presenting indications per medical industry norms to enhance professionalism and ensure the provision of accurate health-care information to medical professionals and patients. The updated versions also reflect the ongoing evolution of TCM terminology and, hence, the urgent need for constant international standardisation efforts.

In Malaysia, multi-languages and multi-cultures interact with one another in a harmonious manner. Bilingual and even multilingual texts in the packaging of TCM products compete for space to provide health information for consumers. The intermingling of Chinese characters with English and/or Malay in the packaging of TCM products tells us a great deal about the complexity of translation under legal constraints. The findings suggest a correlation between the legal constraints of local government and the translation strategies adopted, and hence the resulting translation variations. A key observation and contribution from this investigation is the recognition that the translation of TCM-related terms not only faces linguistic and cultural challenges but also needs to adapt to legal requirements.

Due to the limited sample size, it might be difficult to determine if these findings are representative of TCMS sold in Malaysia as a whole. Future studies could compare and analyse how the packaging of TCMS and health supplements is translated into English and other languages, how the packaging of the same TCM products is translated and restricted by different jurisdictions, and how practitioners, patients, or consumers perceive and receive TCM packaging translations to offer insights on translation quality assurance.

Notes

1. Xuanming Lunfang, known as Huangdi Suwen Xuanming Lunfang, is a famous formula book written by Wansu Liu in Jin Dynasty (1115–1234).
2. Shen Nong Ben Cao Jing (Shen Nong's Herbal), sometimes translated as The Divine Farmer's Materia Medica, is a Chinese book on agriculture and medicinal plants, traditionally attributed to Shennong.
3. The sample was collected from the website of Eu Yan Sang 余仁生 (https://www.euyansang.com.my/en_MY/home) and Sung Khong 顺康 (<https://www.sungkhong.com.my/>) as follows. **Eu Yan Sang** 余仁生: Capsules Of Cordyceps Sinensis Mycelia 冬虫夏草; Ling Zhi 'Cracked' Spores Capsules Plus 灵芝'破壁'孢子胶囊; Kang Du Qing Fei Pills 抗毒清肺丸; Bee Propolis-Plus Cough Nectar 止咳露; Cold & Fever Relief Granules 驱感冒发烧颗粒; Gold Label Bak Foong Pills 金牌白凤丸; Bo Ying Compound 保婴丹; Active Liva Capsules; American

Ginseng Capsule花旗参; Hou Ning Phlegm Relief Powder喉宁化痰散; Qi Ju Di Huang Pills杞菊地黄丸; Luk Mey Pills/Liu Wei Di Huang Pills六味地黄丸; American Wild Ginseng Capsule野生花旗参; So Hup pills蘇合丸; Zhui Feng So Hup pills追風蘇合丸; Pearl Powder珍珠末; An Shen Jun Ging powder安神鎮驚散; RYRChol Capsules紅曲納豆膠囊; Ley Joong Pills理中丸; Bu Qi Jian Zhong Pills补气健中丸; Lok Mei Pa Plus Pills鹿尾羝丸; Jee Pak Ba Wei Pills知柏八味丸; Cold Cough Powder頑固寒咳药粉; Hot Cough Powder頑固热咳药粉; Mild Hot Cough Powder轻微热咳药粉; Mild Cold Cough Powder轻微寒咳药粉; NIN JIOM PEI PA KOA蜜炼川贝枇杷膏; Hou Ning Powder喉宁; Ning Shen Pill宁神丸; CHLORELLA绿藻錠. **Sung Khong** 顺康: CORDYCEPS藏原虫草; LIANHUA QINGWEN JIAONANG莲花清瘟胶囊; RED BRAND Manufactured by Ban Kah Chai红牌追风苏合丸; TIAN QI龙田七; YINQIAO TABLET银翘片; BAI FENG WAN白凤丸.

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