Development and Validation of a Questionnaire to Evaluate the Knowledge on Registered Medicinal Products Among Healthcare Personnel in Perlis

Wang Lynn Choy[1*], Amira Mohamad Jelani[1], Ming Yi Goh[1], Nurul Syafini Arbaen[1], Muhammad Fathi Aizad Mahmud[1], Sasidharan Nair Raman[1], Mohd Shainol Azmar Kassim[1], Pei Pei Soo[1], Yit Han Ng[2]

[1]*Pharmaceutical Services Division, Perlis State Department of Health, Jalan Raja Syed Alwi, 01000 Kangar, Perlis, Malaysia*
[2]*Department of Social and Preventive Medicine, Faculty of Medicine, Universiti Malaya, 50603 Kuala Lumpur, Malaysia*

Correspondence to: Wang Lynn Choy (choywanglynn@moh.gov.my)

Received: 1 April 2025
Accepted: 8 April 2026

ABSTRACT

Introduction:
In Malaysia, all medicinal products must be registered with the Ministry of Health (MOH). However, unregistered products continue to circulate, posing a risk to public health. Healthcare personnel play a vital role in ensuring only registered medicinal products are used in clinical practice. This study aimed to develop and validate a questionnaire to assess the knowledge of registered medicinal products among healthcare personnel in Perlis.

Methods:
The study employed a four-phase process: (1) item generation through literature review and expert consultation; (2) content validity assessment by six experts; (3) pilot testing by healthcare personnel; and (4) construct validity and reliability testing.

Results:
An initial 30-item knowledge questionnaire was developed in English and Malay. Language accuracy was reviewed by two local experts. Content validation led to the removal of two items, while the pilot study incorporating face validation retained the remaining 28 items. One item was excluded prior to factor analysis. Exploratory factor analysis removed 15 items and identified five domains: Product Registration in Malaysia, Registration Numbers & Requirements for Product Registration, Hologram Security Label, Current Requirements for SIRIM and Halal Labels, and Product Registration Categories. The final validated questionnaire consisted of 12 items.

Conclusion:
The 12-item questionnaire demonstrated a validated structure for future research and initiatives aimed at enhancing healthcare personnel's knowledge on registered medicinal products in Malaysia. However, domains 2 (Registration Number and Requirements for Product Registration), 3 (Hologram Security Label), and 5 (Product Registration Categories) showed inadequate internal consistency, indicating the potential for further refinement.

Keywords:
Healthcare personnel, validation, questionnaire, registered medicinal products

INTRODUCTION

In Malaysia all medicinal products (mentioned as "products" in this article) including pharmaceutical products, health supplements and traditional preparations must be registered with the Drug Control Authority (DCA), Ministry of Health (MOH) prior to their sale and use.[1] The National Pharmaceutical Regulatory Agency (NPRA) acts as the secretariat to the DCA and is responsible for the registration process of products in Malaysia. This regulatory measure ensures that all products are thoroughly evaluated for safety, efficacy, and quality prior to their introduction into the market.

Registered products in Malaysia must display both a product registration number and a hologram security label to indicate compliance with these regulatory requirements.[1] The registration number is a unique identification number assigned by NPRA upon product registration. It begins with "MAL", followed by a four-digit code representing the year and month of registration, a four-digit serial number, and a letter indicating the product category: "A" for scheduled poisons, "B" for natural products with therapeutic claims, "X" for non-scheduled poisons, "N" for health supplements, and "T" for natural products, including traditional and homeopathic medicines.[1,2] The hologram security label, affixed to the packaging or product, assists in verifying authenticity.[3]

Unregistered products have not undergone the various stages of assessment and testing by NPRA and hence their safety, efficacy and quality are unestablished.[4,5] Consequently, consuming these products may not give rise to the desired medicinal effects and may even be detrimental to the health of consumers.[6] According to a report by the Emerging Markets Health Network in 2013, the prevalence of counterfeit medicines in Malaysia was approximately 3 to 5% and the trend was expected to continue to rise.[7] Between 2019 and 2021, the Pharmaceutical Enforcement Division (PED) of the Ministry of Health confiscated unregistered products valued at over RM5.8 million during nationwide raids.[8] This issue persisted in 2022, with seizures of unregistered products exceeding RM5.2 million.[9] Most recently, in July 2024, the PED seized illegal medicines worth RM4.4 million in Penang, Kedah, and Johor[10], further highlighting the

continued prevalence of unregistered medicines in Malaysia. Hence, *Tolak Ubat Tidak Sah* (TOBaTS) campaign was initiated by the PED in May 2024 to combat the issue of sale and supply of illegal products in Malaysia.[11]

Given the persistence of this issue, healthcare professionals play a crucial role as guardians of public health and well-being. They are expected to possess in-depth knowledge of medicinal products used to diagnose, treat, and cure health conditions. According to the 2015 National Survey on the Use of Medicines by Malaysian Consumers, 58.6% of respondents preferred consulting government sector doctors for health-related issues[12], underscoring the trust placed in healthcare workers as key sources of information on health matters. To effectively fulfil their role, healthcare professionals must not only serve as role models but also be well-versed in the use of registered products and the enforcement of relevant laws, enabling them to better guide and protect the public.

There have been studies evaluating the knowledge level of healthcare personnel on registered products in other Malaysian states. A study conducted in Labuan assessed the knowledge of government healthcare personnel regarding registered products and notified cosmetics.[13] However, it included outdated regulatory elements, particularly the Meditag™ hologram label system, which was replaced by the more advanced FarmaTag® in 2019.[3] To support this, the FarmaChecker™ mobile application was also introduced, enabling users to verify a product's authenticity by scanning the FarmaTag® label.[3] Hence, a new questionnaire is necessary.

Therefore, we aimed to develop and validate a new, valid, and reliable questionnaire to evaluate the knowledge level of healthcare personnel towards registered products. We believe that understanding the knowledge of healthcare personnel may help in planning future educational programmes for healthcare personnel regarding registered products in Malaysia.

METHODS

The process of development and validation of the questionnaire was undertaken in four phases: Phase 1, generating items for the questionnaire; Phase 2, content validation; Phase 3, pilot study; and Phase 4 construct validity and reliability testing of the questionnaire.

Phase 1: Questionnaire development

The questionnaire consisted of sections on socio-demographic background, practice, and knowledge on registered products. It was developed based on relevant literature and expert input. A panel of senior pharmacy enforcement officers in Perlis contributed to the construction of the initial knowledge items, ensuring alignment with current regulatory practices in Malaysia. The items were developed bilingually in Malay and English by the researchers, who conducted simultaneous translation during the drafting process. Language accuracy and clarity were subsequently reviewed by two independent local language experts.

Phase 2: Content validity

The questionnaire was sent to six experts in the field of enforcement, regulatory, and pharmacy practice to assess the content validity, which was assessed using the Content Validity Index (CVI), which included both item-level CVI (I-CVI) and scale-level CVIs: S-CVI/Ave and S-CVI/UA. The I-CVI was calculated as the proportion of experts rating an item as either 3 or 4 on a 4-point relevance scale (1 = Not relevant, 2 = Somewhat relevant, 3 = Quite relevant, 4 = Highly relevant). Only ratings of 3 or 4 were considered "relevant."

The I-CVI was computed as:

$$\text{I-CVI} = \frac{\text{Number of experts rating the item as relevant}}{\text{Total number of experts}}$$

The scale-level CVIs were calculated as follows:

$$\text{S-CVI/Ave} = \frac{\text{Sum of I-CVI for all items}}{N}$$

$$\text{S-CVI/UA} = \frac{\text{Number of items with universal agreement}}{N}$$

where *N* is the total number of items.

Universal agreement (UA) was defined as all experts rating an item as relevant (i.e., a rating of 3 or 4). An item received a UA score of 1 if all experts rated it as relevant, and 0 if otherwise. A CVI value greater than 0.83 was considered acceptable for a panel of six experts.[14]

Phase 3: Pilot study

A pilot study incorporating face validation was conducted with 30 respondents from diverse backgrounds, including medical doctors, dentists, pharmacists, medical assistants, pharmacy assistants, and nurses serving in MOH facilities in Perlis. The reviewed questionnaire was distributed in person. The respondents were asked to answer each item, and to provide written feedback on item clarity, suitability and comprehensibility. The time taken to complete the questionnaire was also recorded.

Phase 4: Construct validity and reliability

The final questionnaire consisted of 28 items. A minimum sample size of 140 participants was calculated based on the rule of thumb of 1:5 respondents per item, given that the questionnaire consisted of 28 items.[15] With an additional 20% dropout rate, the sample size was estimated to be 175 respondents.

Inclusion criteria for the study were healthcare personnel from all schemes working in the public sector in Perlis, adults aged 18 and above. Healthcare personnel who were on long leave (e.g.

maternity leave, study leave) and who were not fully registered with the governing bodies during the study period were excluded from this study. The self-administered questionnaire was digitally distributed to all healthcare personnel working in the public sector in Perlis via Google Forms (see Appendix A). The list of knowledge domain questions is provided in Appendix B. In this phase, we recruited a total of 190 respondents.

Data was analysed using Jamovi software version 2.5.7.[17] The suitability of the dataset for factor analysis was evaluated using the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity. Parallel analysis was conducted to determine the appropriate number of factors to extract. Exploratory factor analysis (EFA) was performed using Maximum Likelihood extraction and Oblimin rotation. Reliability testing was carried out using Cronbach's alpha coefficient to assess the internal consistency of the final factor structure.

Acceptable values for exploratory factor analysis were set as follows: a KMO value of ≥ 0.5 to indicate adequate sampling[16], and a significant Bartlett's Test of Sphericity ($P < 0.05$) to confirm sufficient inter-item correlations.[18] A factor loading cutoff of ≥ 0.3 was used for item retention[19], while a Cronbach's alpha value of ≥ 0.5 was considered acceptable for internal consistency or reliability.[20-23]

RESULTS

Phase 1: Questionnaire development

Following an extensive literature review[2,3,4,11,13], a questionnaire was developed by the expert panel comprising 12 items on socio-demographic characteristics, 3 items on practice, and 30 items on knowledge. Item generation was guided by a review of relevant sources, including Malaysian regulatory guidelines such as the Drug Registration Guidance Document (DRGD)[2], which outlines the requirements and categories of product registration. National regulatory tools like the updated hologram system FarmaTag®, which replaced Meditag™ in 2019[3], were also incorporated to reflect current verification procedures. In addition, public education materials such as MyHealth articles on the importance of using registered products[4], and recent public awareness campaigns like TOBaTS launched in 2024[11], were reviewed to ensure alignment with evolving enforcement efforts and public messaging.

Three prior questionnaires were reviewed during item generation. These included a 12-item tool developed by Tan[13] for Malaysian government healthcare personnel in Labuan, which provided a useful foundation for identifying key areas of regulatory knowledge. However, this tool contained outdated elements such as the Meditag™ hologram and did not reflect recent updates, including the introduction of FarmaTag®, digital verification apps (e.g., FarmaChecker™), and the use of SIRIM and Halal certification logos. Two additional instruments by Zulkifli et al.[24,25] in Malaysia were identified but were developed for a different target population, which were members of the public or patients, and were therefore not directly applicable to this healthcare personnel-focused study.

All items were newly developed and refined by the expert panel in consultation with senior pharmacy enforcement officers in Perlis, with a focus on current Malaysian regulatory practices, healthcare professional-level knowledge, and known gaps in practice.

The list of knowledge items aimed to comprehensively assess healthcare personnel's understanding across multiple domains, including product registration requirements, security features, product categories, legal supply chains, and enforcement regulations for registered medicines. Each item offered two response options, and respondents were required to select only one. The responses were then scored on a dichotomous scale of "Correct answer" and "Incorrect answer".

The questionnaire was prepared in both Malay and English to enhance accessibility for healthcare personnel. Language accuracy and clarity were reviewed by two independent local language experts. However, a formal translation procedure, such as forward–backward translation, was not conducted. Revisions suggested by the language experts were minimal and are summarised in the table in Appendix C.

Phase 2: Content validity

Six experts reviewed the questionnaire and recommended removing two knowledge items: Q3 ("Medicines registered in Malaysia must comply with the Drug Registration Guidance Document issued by NPRA") due to limited relevance for healthcare professionals, and Q6 ("MAL registration number is one of the characteristics of a registered medicine") due to redundancy as it was deemed similar to Q4 and Q5. The remaining 28 knowledge items (renumbered as K1 to K28) achieved strong content validity, with an S-CVI/Ave score of 0.96 and S-CVI/UA of 0.83. Several items including Q1, Q2, Q15, Q16, Q19, Q22, Q30 were rephrased for improved clarity. A summary table of the revisions is provided in Appendix D.

Phase 3: Pilot study

The revised 28-item questionnaire underwent pilot study incorporating face validity testing with 30 healthcare personnel from public healthcare facilities. All respondents reported that the questionnaire was clear, suitable, and easy to understand. Two respondents provided feedback suggesting minor modifications, which led to the rephrasing of one knowledge item (K19) to improve clarity while maintaining the original intent of the question. No items were removed or added during this phase. The average time to complete the questionnaire was approximately 15 minutes. The revision made to item K19 is summarised in the table in Appendix E.

Phase 4: Construct validity and reliability

The socio-demographic characteristics of the 190 respondents are presented in Table 1. The mean age was 41.11 years (SD=8.34). The majority of the respondents were female (75.8%), Malay (93.7%), and married (77.9%). Majority of them possessed diploma qualification (36.8%) and worked as nurses (29.5%). Respondents primarily worked in health clinics (37.9%). More than half of the respondents had working experiences of 6-19 years (50.5%). Almost half of the respondents (48.4%) were in the M40 income group. A majority (74.7%) reported no history of chronic illnesses and lived in urban areas (57.4%). Notably, 78.4% of respondents reported having previously verified a medicinal product's registration status with the MOH before purchasing.

Table 1. Socio-demographic characteristics of respondents (n=190)

Variables	n (%)
Age (Years); Mean±SD	41.11±8.34
Gender	
Male	46 (24.2)
Female	144 (75.8)
Race	
Malay	178 (93.7)
Chinese	7 (3.7)
India	3 (1.6)
Others	2 (1.1)
Marital Status	
Single	29 (15.3)
Married	148 (77.9)
Others	13 (6.8)
Highest Education Level	
SPM	37 (19.5)
Diploma	70 (36.8)
Bachelor's Degree	69 (36.3)
Master's Degree	14 (7.4)
Occupation	
Medical doctors	20 (10.5)
Dentists	7 (3.7)
Pharmacists	31 (16.3)
Medical and pharmacy assistants	7 (3.7)
Nurses	56 (29.5)
Other clinical personnel	34 (17.9)
Non-clinical personnel	35 (18.4)
Workplace	
State Department of Health	59 (31.1)
Hospital	59 (31.1)
Health Clinics	72 (37.9)
Duration of Service (years)	
≤5	27 (14.2)
6-19	96 (50.5)
≥20	67 (35.3)
Estimated Monthly Household Income (RM)	
≤4,849 (B40)	74 (38.9)
4,850 – 10,959 (M40)	92 (48.4)
≥10,960 (T20)	24 (12.6)
History of Chronic Illness	
Yes	48 (25.3)
No	142 (74.7)
Living Area	
Urban	109 (57.4)
Non-urban	81 (42.6)
Have you verified a medicinal product's registration with MOH before purchasing?	
Yes	149 (78.4)
No	41 (21.6)

n=frequency; SD=standard deviation

Prior to analysis, item K28 (Supplying/selling unregistered medicines is punishable by law) was excluded because descriptive statistics revealed that all respondents answered it correctly, resulting in zero variance. This reduced the total number of knowledge items from 28 to 27 (K1 to K27) for subsequent analysis.

The suitability of the dataset for factor analysis was first assessed. The KMO measure of sampling adequacy was 0.452, and Bartlett's Test of Sphericity was significant ($P < 0.001$). A parallel analysis supported the extraction of five factors.

EFA was then performed on the remaining 27 items using maximum likelihood extraction and oblimin rotation. Based on the results, 15 items were removed due to various issues, including low or suppressed factor loadings (i.e., values below 0.3 that appeared as blank cells in the pattern matrix; factor loadings reflect how strongly an item correlates with a latent factor), negative factor loadings indicating weak or inverse associations with the factor, and cross-loadings, where a single item loaded ≥ 0.3 on two or more factors, making it difficult to assign the item to a specific domain. Table 2 presents the factor loadings of the 12 retained items across five extracted factors, along with their uniqueness values. Each item strongly loaded onto only one factor (≥ 0.3), confirming the distinctiveness of the resulting domains and supporting the structural validity of the revised questionnaire.

Table 2. Factor loadings of each item based on factor analysis

Item	Factor					Uniqueness
	1	2	3	4	5	
K1	0.972					0.005
K3	0.774					0.358
K7		0.994				0.005
K6		0.705				0.505
K17			0.684			0.506
K18			0.628			0.606
K4			0.482			0.637
K19			0.367			0.761
K12				0.987		0.005
K10				0.403		0.811
K5					0.992	0.005
K14					0.316	0.828

Note: 'Maximum likelihood' extraction method was used in combination with an oblimin rotation

The final 12-item version of the questionnaire was retained based on a clear and interpretable factor structure. These 12 items were grouped into five domains: Domain 1 - Product Registration in Malaysia (K1 and K3); Domain 2 - Registration Number and Requirements for Product Registration (K4, K17, K18, and K19); Domain 3 - Hologram Security Label (K5 and K14); Domain 4 - Current Requirements for SIRIM and Halal Labels (K6 and K7); and Domain 5 - Product Registration Categories (K10 and K12).

Reliability analysis was subsequently conducted on the final 12-item scale using Cronbach's alpha. The reliability coefficients for each domain were as follows: 0.799 for Domain 1, 0.609 for Domain 2, 0.456 for Domain 3, 0.820 for Domain 4, and 0.540 for Domain 5.

The responses to the final 12-item questionnaire were summarised according to their respective domains, along with the proportion of correct and incorrect answers, as shown in Table 3. Each domain's internal consistency was also reported using Cronbach's alpha.

The overall process of the questionnaire development and validation is summarised in Figure 1.

Table 3. Knowledge responses by item and domain with Cronbach's alpha values

	Items	Correct, n (%)	Incorrect, n (%)	Cronbach's alpha
Domain 1. Product registration in Malaysia				0.799
K1	It is mandatory for medicines in Malaysia to undergo registration with the Ministry of Health Malaysia (MOH).	188 (98.9)	2 (1.1)	
K3	All registered medicines in Malaysia have registration numbers.	189 (99.5)	1 (0.5)	
Domain 2. Registration numbers & Requirements for product registration				0.609
K4	Medicine registration numbers in Malaysia begin with 'MAL'.	185 (97.4)	5 (2.6)	
K17	All creams used to treat skin diseases are required to be registered with MOH.	184 (96.8)	6 (3.2)	
K18	Medicated oils for external use are required to be registered with MOH.	168 (88.4)	22 (11.6)	
K19	Traditional medicines in the forms of liquid, capsules, tablets or others are required to be registered with MOH.	185 (97.4)	5 (2.6)	
Domain 3. Hologram security label				0.456
K5	Hologram security label is one of the characteristics of a registered medicine.	185 (97.4)	5 (2.6)	
K14	Which one of the hologram security labels is mandatory on medicine packaging? -Label A: SIRIM -Label B: FarmaTag®	176 (92.6)	14 (7.4)	

Table 3. Continued

	Items	Correct, n (%)	Incorrect, n (%)	Cronbach's alpha
Domain 4. Current Requirements for SIRIM and Halal labels				0.820
K6	SIRIM certification label is one of the characteristics of a registered medicine.	88 (46.3)	102 (53.7)	
K7	JAKIM Halal label is one of the characteristics of a registered medicine.	93 (48.9)	97 (51.1)	
Domain 5. Product registration categories				0.540
K10	MAL registration numbers that end with the letter X (e.g. MAL12345678X) refer to Non-Scheduled Poisons or Over-The Counter (OTC) Medicines.	174 (91.6)	16 (8.4)	
K12	MAL registration numbers that end with the letter N (e.g. MAL12345678N) refer to Health Supplements.	173 (91.1)	17 (8.9)	

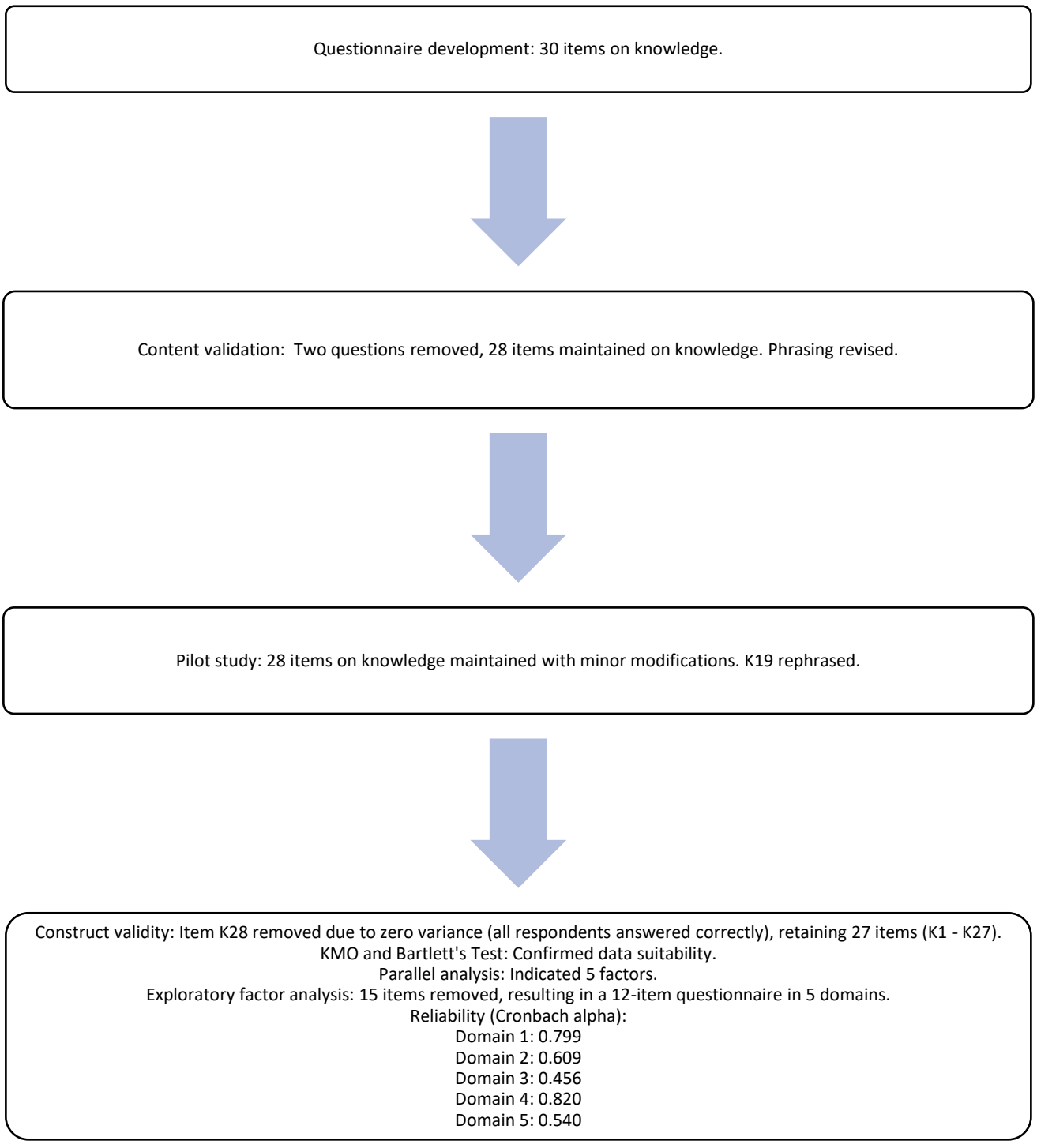


Figure 1. Questionnaire development and validation process

DISCUSSION

Overall summary

This study successfully developed and validated a concise, 12-item bilingual questionnaire to assess the knowledge of healthcare personnel in Perlis regarding registered medicinal products. Content validity was established through expert evaluation, resulting in the removal of two items. Pilot study incorporating with face validity testing confirmed that the remaining items were clear, relevant, and appropriately worded. Exploratory factor analysis supported the construct validity of the instrument, yielding a five-domain structure with acceptable factor loadings ranging from 0.316 to 0.994. Internal consistency reliability testing showed acceptable Cronbach's alpha values across domains, except for domains 2, 3 and 5. Overall, the final questionnaire demonstrated good content coverage, practical relevance, and alignment with current Malaysian regulatory standards, with potential refinement for domains with Cronbach's alpha of below 0.70.

Phase 1: Questionnaire generation

The development of the initial questionnaire was grounded in local regulatory sources and frontline enforcement experience, ensuring strong contextual relevance. References such as the DRGD and NPRA materials on FarmaTag® provided the technical basis, while public campaigns like TOBaTS helped shape items related to community-facing enforcement issues.

The decision to reference Tan[13] allowed identification of persistent knowledge gaps, particularly regarding supply chain verification and counterfeit detection. However, outdated elements in Tan's tool (e.g., Meditag™) necessitated new item development to reflect evolving practices. In addition, other existing tools by Zulkifli et al. were primarily developed for the public population[24,25] and lacked the depth required for healthcare professionals, who are expected to understand regulatory procedures and product verification in greater detail. Overall, the inclusion of updated and diverse references strengthened the content coverage and practical relevance of the initial questionnaire draft. Notably, no international tools were identified that aligned with Malaysia's unique regulatory environment, further justifying the need for a locally developed instrument.

The questionnaire was prepared in both Malay and English to accommodate the language preferences of healthcare personnel. Language accuracy was reviewed by two independent local language experts to ensure clarity and contextual relevance. Only minor adjustments were proposed during this review, reflecting the initial clarity of the bilingual drafting process. However, a formal translation protocol, such as forward–backward translation, was not implemented due to time constraints and the limited scale of this pilot study. This may introduce potential construct or item bias, as noted by Hambleton et al.[26], who emphasised the importance of rigorous translation procedures in maintaining test validity across languages.

Phase 2: Content Validity

The content validation process showed that most items were rated as highly relevant by experts in regulatory and enforcement pharmacy. The removal of Q3 and Q6 helped improve the questionnaire by ensuring the knowledge items were more suitable for healthcare professionals. Q6 was removed because it overlapped with Q4 and Q5, which also addressed MAL registration numbers, helping to reduce redundancy. Several other items were reworded based on expert feedback to improve clarity and make the questionnaire easier to understand. These changes likely contributed to the high S-CVI/Ave score of 0.96, indicating strong agreement among experts on item relevance. Overall, this phase helped improve the quality and content coverage of the questionnaire.

Phase 3: Pilot study

The revised 28-item questionnaire was tested for face validity among 30 healthcare personnel from diverse settings. Most respondents found the questionnaire easy to understand and appropriate for its intended purpose. Feedback from two participants led to the rephrasing of item K19 to improve clarity and include a wider range of medicinal dosage forms. The estimated completion time of around 15 minutes suggests the tool is practical and feasible for routine use in healthcare settings.

Phase 4: Construct validity and reliability

Construct validity was assessed through exploratory factor analysis (EFA) using responses from 190 respondents.

Additionally, item K28 ("Supplying/selling unregistered medicines is punishable by law") was removed prior to inferential analysis. Despite its importance, this item demonstrated zero response variance, as all respondents answered it correctly. The lack of variability suggested that the item did not effectively discriminate between different levels of knowledge. Its removal was justified, as the uniform response pattern reflected a well-established awareness among healthcare personnel of this legal provision. Consequently, the number of knowledge items analysed was reduced from 28 to 27, resulting in items K1 to K27.

The KMO value was 0.452, reflecting suboptimal sampling adequacy[16], though Bartlett's Test of Sphericity remained statistically significant ($P < 0.001$), suggesting that correlations among items were sufficient for factor analysis. A parallel analysis was also conducted and supported the extraction of five factors. The KMO value of 0.452 indicates marginal sampling adequacy for factor analysis, falling slightly below the commonly recommended threshold of 0.50. While Bartlett's Test of Sphericity was statistically significant ($P < 0.001$), indicating sufficient inter-item correlations, the relatively low KMO suggests that the shared variance among items may be limited. Nevertheless, parallel analysis supported the extraction of five factors, and the resulting factor structure demonstrated conceptual

interpretability and acceptable loading patterns. Therefore, the findings from the exploratory factor analysis should be interpreted with caution, and further validation using larger and more heterogeneous samples is recommended to confirm the stability and robustness of the factor structure.
EFA was performed using maximum likelihood extraction with oblimin rotation, which is suitable when underlying constructs are expected to be correlated. Items were removed based on established criteria, including low factor loadings (< 0.3), negative or non-significant loadings, and cross-loadings on multiple factors that made domain interpretation ambiguous. This process led to the exclusion of 15 items and resulted in a refined 12-item questionnaire with a cleaner, more interpretable factor structure.

The final instrument captured five distinct domains aligned with the conceptual framework of the study: (1) Product Registration in Malaysia; (2) Registration Numbers and Requirements for Product Registration; (3) Hologram Security Label; (4) Current Requirements for SIRIM and Halal Labels; and (5) Product Registration Categories. These domains reflect key areas of knowledge relevant to the healthcare personnel's understanding of registered medicinal products in Malaysia.

Domain 1 focused on the fundamental requirement for medicines to be registered with the Ministry of Health (MOH), forming a baseline of regulatory knowledge for healthcare personnel. Items K1 ("It is mandatory for medicines in Malaysia to undergo registration with MOH") and K3 ("All registered medicines in Malaysia have registration numbers with MOH") were included to reinforce these foundational principles. The domain showed good internal consistency (α = 0.799), indicating that these factual and well-structured items elicited consistent responses across all respondents.

Domain 2 covered knowledge on registration numbers and the types of products requiring registration. Items K4 and K17 to K19 addressed key concepts, such as the "MAL" number prefix and common products encountered in healthcare settings including therapeutic creams (K17), medicated oils (K18), and traditional dosage forms like capsules or tablets (K19). This domain achieved borderline reliability (α = 0.609), which reflects questionable internal consistency[20], but could probably be acceptable given the small number of items. Cronbach's alpha values below 0.5 is common for short scales with fewer than 10 items.[21] The retained items reflect essential regulatory criteria and are highly relevant for frontline healthcare personnel.

Domain 3 assessed recognition of the mandatory hologram security label (FarmaTag®), which, along with the "MAL" registration number, is a defining feature of registered products. Item K5 highlighted the function of the hologram as an authenticity marker, while K14 required respondents to identify the correct hologram type. In both items, images of various hologram labels were provided to test respondents' ability to visually recognise the correct symbol. Despite the use of images to aid identification, Domain 3 showed the lowest internal consistency (α = 0.456), likely because the two items may be measuring different aspects of knowledge regarding the hologram rather than a single underlying construct. Future iterations of the questionnaire may benefit from adding more items to this domain or re-evaluating whether these two items should be treated as separate subdomains.

Furthermore, FarmaTag® was introduced in 2019[3], and many respondents may be unfamiliar with it due to limited publicity and lack of widespread promotion. The specificity of visual content and the requirement to recognise a relatively new label could lead to increased guessing or uncertainty during item response, reducing the reliability of this scale. As supported by previous literature, unfamiliar content and items that induce guessing can reduce internal consistency.[27]

Nonetheless, the domain was retained due to its strong importance and relevance in evaluating awareness of current regulatory packaging features, which healthcare personnel must be able to recognise and communicate to patients. Prior work suggests that Cronbach's alpha values above 0.3 may still reflect that an assessment has balanced and valid test items.[22] This supports the retention of domains with few items or recently introduced content, such as the FarmaTag® label.

Domain 4 targeted common misconceptions regarding the relevance of SIRIM (K6) and Halal (K7) logos on medicine packaging. Both items recorded high incorrect response rates (K6: 53.7%; K7: 51.1%), reflecting widespread misunderstanding among healthcare personnel. These items are important for correcting false beliefs such as assuming that these logos are required for product registration. In fact, the SIRIM logo is not permitted on product labels due to its annually renewed certification, which conflicts with the 5-year validity period of product registration.[2] Similarly, while the Malaysian government is working to promote the growth of halal pharmaceuticals[28], currently the use of the Halal logo is optional and applicable only to non-scheduled poisons (excluding veterinary products), health supplements, and natural products. Scheduled poisons marketed locally are not permitted to display the Halal logo.[2] The domain exhibited good internal consistency (α = 0.820), supporting its retention despite the high error rates, which actually underscore its relevance in identifying knowledge gaps.

Domain 5 included items K10 and K12, which focused on Over-the-Counter (OTC) products (MAL number ending in "X") and health supplements (MAL number ending in "N"), respectively. Although items on controlled medicines ("A") and traditional medicines ("T") were initially considered (K8 and K11), they were excluded due to high correct response rates (K8: 96.3%; K11: 94.2%), indicating these concepts were already well understood. This could be due to the fact that healthcare personnel

mainly deal with controlled medicines (e.g., MAL12345678A) in their daily work and the letter "T" is the initial for traditional medicines, which is a telling characteristic of its registration number (e.g. MAL12345678T). In contrast, K10 and K12 had slightly lower correct rates (K10: 91.6%; K12: 91.1%), suggesting room for improvement. The internal consistency for Domain 5 was low (α = 0.540)but is acceptable for a two-item scale in an exploratory context.[21,23] These items remain crucial for distinguishing between product categories and interpreting registration number suffixes.

Beyond statistical considerations, the item reduction process was also guided by conceptual relevance. Eight items (K20 to K27) addressing the locations where registered products can be obtained were removed, as they were considered redundant and potentially confusing. This decision was appropriate, as identifying specific purchasing locations was deemed insignificant to the study's objectives. The primary focus of the questionnaire was to assess healthcare personnel's knowledge of the characteristics and categories of registered products, rather than the exact locations where they could be purchased.

Items K13 (methods to check registration status) and K15 (application to verify hologram security label) were not included the final questionnaire as majority of the respondents answered them correctly (K13: 97.9%, K15: 91.6%). The target population for this questionnaire was healthcare personnel and they were deemed to be familiar with the methods used to verify a product's registration status. This removal was supported by the final socio-demographic item (a practice item initially) as majority of the respondents (78.4%) answered that they have verified products' registration statuses before purchasing them. In addition, many awareness campaigns including exhibitions and social media postings have been conducted in recent years to advocate the use of the "NPRA Product Status" and "FarmaChecker™" applications to check for products' registration statuses and hologram security labels' authenticity. The methods and application used to check for these features were considered well-known among healthcare personnel and their knowledge was not required to be assessed in the questionnaire.

The final questionnaire comprised 12 items distributed across five knowledge domains, each with acceptable Cronbach's alpha values.[21,22] These domains were deemed appropriate as they encompassed a comprehensive range of items relevant to assessing healthcare personnel's knowledge of registered products.

In addition to statistical and conceptual considerations, item reduction was guided by practical concerns. Studies have suggested that questionnaires should not exceed 15–20 items to maintain respondent engagement and minimise response fatigue.[29] Lengthy, multi-item questionnaires can overwhelm respondents, potentially reducing response rates and compromising data quality.[30-33] It was therefore agreed that a shorter, more concise questionnaire would be more user-friendly, requiring less time to complete and improving both participation and the accuracy of responses. This aligns with the final structure of the questionnaire, which retained 12 essential knowledge items across five domains.

Revisions to practice items in questionnaire analysis

Although three practice-related items were initially included in the questionnaire, only one item i.e. "Have you verified a medicinal product's registration with MOH before purchasing?" was ultimately retained. This item was considered directly aligned with the study objectives and served to contextualise respondents' prior exposure to the topic. In contrast, the other two items were excluded due to limited relevance: one was overly broad (e.g., prior purchase of medicines), while the other was too specific (e.g., use of the FarmaChecker™ app), offering minimal additional value to the overall analysis. The retained item was not intended to evaluate practice behaviour as a separate domain, but was instead treated as a background characteristic and analysed descriptively with the socio-demographic data.

Study strengths

A concise 12-item questionnaire was developed and validated, offering a brief yet comprehensive tool to assess healthcare personnel's knowledge of registered products. The findings from this study can help inform the development of future awareness programs targeting healthcare personnel across Malaysia.

Study limitations

The study had several limitations. The initial questionnaire development involved only pharmacy enforcement officers from Perlis, which may limit the generalisability of the findings. Additionally, the content validation process did not include input from academic experts, which could have enhanced the validity of the questionnaire. Furthermore, the use of dual-language questionnaires without formal translation procedures may have introduced minor language-related bias.[26]

Future work

In the future, it is recommended that further analyses, such as Item Response Theory or Confirmatory Factor Analysis, be conducted to validate the questionnaire. To address the limitations of this study, future validation studies across diverse geographical regions and practice settings, such as personnel working in the private sector, are recommended to further establish the generalisability of the instrument.

CONCLUSION

The 12-item questionnaire demonstrated a validated structure for future research and initiatives aimed at enhancing healthcare personnel's knowledge on registered medicinal

products in Malaysia. However, domains 2 (Registration Number and Requirements for Product Registration), 3 (Hologram Security Label), and 5 (Product Registration Categories) showed inadequate internal consistency, indicating the potential for further refinement.

ACKNOWLEDGEMENT

The authors thank the Director General of Health, Malaysia for his permission to publish this article. The authors also thank Perlis State Pharmaceutical Services Division, Pharmaceutical Services Programme, NPRA, Clinical Research Centre Hospital Tuanku Fauziah and everyone involved in the study for their contribution.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

FUNDING

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

ETHICAL APPROVAL

This study was reviewed and obtained ethical approval from the Medical Research and Ethics Committee, Ministry of Health Malaysia. [Study ID: NMRR ID-23-01996-M0T (IIR)].

REFERENCES

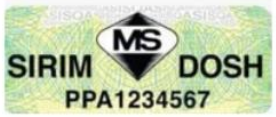
1. Pharmaceutical Services Programme. How to identify medicines that are registered with MOH? [Internet]. [cited 2023 May 13]. Available from: https://www.pharmacy.gov.my/v2/en/faq/how-identify-medicines-are-registered-moh.html
2. National Pharmaceutical Regulatory Agency. Drug Registration Guidance Document (DRGD) Third Edition Ninth Revision [Internet]. 2025 [cited 2025 Mar 11]. Available from: https://www.npra.gov.my/index.php/en/component/sppagebuilder/925-drug-registration-guidance-document-drgd.html
3. Program Perkhidmatan Farmasi. Label Keselamatan Hologram FarmaTag™ [Internet]. 2021 [cited 2023 May 13]. Available from: https://www.pharmacy.gov.my/v2/ms/entri/label-keselamatan-hologram-farmatagtm.html
4. PORTAL MyHEALTH. Why should you use registered medicines? [Internet]. 2012 [cited 2023 May 13]. Available from: http://www.myhealth.gov.my/en/why-should-you-use-registered-medicines/
5. Ong SC, Vasan Thakumar A, Ooi GS, Shafie AA, Ahmad Hassali MA. Perspectives of the public on the consumption of unregistered health products in Malaysia. Int J of Phar Prac. 2020;28(6):579–90.
6. MPS Young Pharmacist Chapter. Check First, Consume Next: Unregistered Products [Internet]. [cited 2023 May 13]. Available from: https://mpsypc.com.my/publications/unregistered-products/
7. The Borneo Post. 3 to 5 per cent of medicines in Malaysia fake [Internet]. 2013 [cited 2023 May 13]. Available from: https://www.theborneopost.com/2013/02/14/3-to-5-per-cent-of-medicines-in-malaysia-fake-emhn/
8. The Star. Health Ministry: Unregistered products worth more than RM6mil seized. [Internet]. 2021 [cited 2023 May 13]. Available from: https://www.thestar.com.my/news/nation/2021/11/10/health-ministry-unregistered-products-worth-more-than-rm6mil-seized
9. New Straits Times. RM5.2m worth of unregistered pharmaceutical products seized between June 23 and July 1. [Internet]. 2022 [cited 2023 May 13]. Available from: https://www.nst.com.my/news/nation/2022/07/817361/rm52m-worth-unregistered-pharmaceutical-products-seized-between-june-23
10. BERNAMA. RM3.9 mln worth of hazardous sex stimulants, cosmetics seized in Penang [Internet]. 2024 [cited 2024 Aug 14]. Available from: https://bernama.com/en/crime_courts/news.php?id=2326249
11. Program Perkhidmatan Farmasi. Kempen Tolak Ubat Tidak Sah (TOBaTS) 2024 [Internet]. 2024 [cited 2024 Aug 14]. Available from: https://pharmacy.moh.gov.my/tobats/
12. Hassali MA, Saleem F. A National Survey On The Use Of Medicines (NSUM) By Malaysian Consumers [Internet]. 2016 [cited 2023 May 13]. Available from: https://pharmacy.moh.gov.my/sites/default/files/document-upload/national-survey-use-medicine-iii-nsum-iii.pdf
13. Tan ZSS. Knowledge level of government healthcare personnel in Labuan towards Registered Product and Notified Cosmetic. Mal J of Phar. 2019;5(1):1-7.
14. Yusoff MSB. ABC of Content Validation and Content Validity Index Calculation. Ed in Med J. 2019;11(2):49–54.
15. Bujang MA, Ghani PA, Soelar SA, Zulkifli NA. Sample size guideline for exploratory factor analysis when using small sample: Taking into considerations of different measurement scales. ICSSBE. 2012;1-5.
16. Wu RMX, Zhang Z, Zhang H, Wang Y, Shafiabady N, Yan W, et al. An FSV analysis approach to verify the robustness of the triple-correlation analysis theoretical framework. Sci Rep. 2023;13(1):9621.
17. The jamovi project. jamovi (Version 2.5.7) [Computer Software]. 2025 [cited 2025 Jul 30]. Available from: https://www.jamovi.org
18. Statistische Beratung Leonardo Miljko. Exploratory Factor Analysis (EFA) - How to interpret KMO and Bartlett´s test [Internet]. 2020 [cited 2025 Jul 30]. Available from: https://www.statistischedatenanalyse.de/images/Exploratory_Factor_Analysis-EFA-How_to_interpret_KMO_and_Bartletts_test.pdf
19. Tavakol M, Wetzel A. Factor Analysis: a means for theory and instrument development in support of construct validity. Int J of Med Edu. 2020;11:245–247.

20. Ahmad N, Slias FA, Hamat M, Mohamed SA. Reliability Analysis: Application of Cronbach's Aplha in Research Instruments. SIG–e-Learning@CS. 2024;114–119.
21. Pallant J. SPSS Survival Manual: A step by step guide to data analysis using IBM SPSS [Internet]. 7th ed. London: Routledge; 2020 [cited 2025 Jul 30]. Available from: https://www.taylorfrancis.com/books/mono/10.4324/9781003117452/spss-survival-manual-julie-pallant
22. Ekolu SO, Quainoo H. Reliability of assessments in engineering education using Cronbach's alpha, KR and split-half methods. Glo J of Eng Edu. 2019;21(1):24–29.
23. Hansjosten H. Leonardo 3.4.5 Scientific accuracy of the methodology [Internet]. 2015 [cited 2024 Aug 9]. Available from: https://leonardo345.com/wp-content/uploads/2019/05/Leonardo_203_4_5__20statistical_20report_202015_20-1.pdf
24. Zulkifli NW, Aziz NA, Hassan YB, Hassali MA, Bahrin NL. Development of validated questionnaire to access public knowledge on registered drugs. Proc - Soc and Beha Sc. 2014;172:749–753.
25. Zulkifli NW, Mohd Yunus MA, Mohamed Mustafa MFR, Kong WE, Lim CY, Ng WH, et al. A Survey on Knowledge of Registered Drugs amongst Patients from the Specialist Clinic, Malaysia. Al-Nah J of Sc. 2019;22(3):26–34.
26. Hambleton RK, Merenda PF, Spielberger CD, editors. Adapting Educational and Psychological Tests for Cross-Cultural Assessment. Psyc Pres. 2004.
27. McCowan RJ, McCowan SC. Item analysis for criterion-referenced tests [Internet]. New York: Center for Development of Human Services. 1999 [cited 2025 July 31]. Available from: https://files.eric.ed.gov/fulltext/ED501716.pdf
28. Gateway S. Malaysia's halal pharmaceutical industry continues stellar growth [Internet]. 2022 [cited 2024 Aug 14]. Available from: https://salaamgateway.com/story/malaysias-halal-pharmaceutical-industry-continues-stellar-growth
29. Minto C, Vriz GB, Martinato M, Gregori D. Electronic Questionnaires Design and Implementation. The Op Nurs J. 2017;11(1):157–202.
30. Aznan M, Aris M, Pasi H, Shaiful M, Shalihin E, Othman U, et al. Translation and Validation of Malay Version of the Simplified Diabetes Knowledge Test (DKT). Mal J of Med and Heal Sc. 2022;18(3):76–84.
31. Robinson MA. Using multi-item psychometric scales for research and practice in human resource management. Hum Res Man. 2018;57(3):739–750.
32. Postmes T, Haslam SA, Jans L. A single-item measure of social identification: Reliability, validity, and utility. Br J of Soc Psy. 2012;52(4):597–617.
33. Wanous JP, Reichers AE, Hudy MJ. Overall job satisfaction: How good are single-item measures? J of App Psy. 1997;82(2):247– 252.

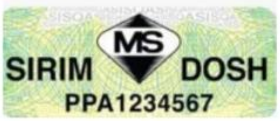
Appendix A. Questionnaire

Link to self-administered questionnaire: https://forms.gle/scvizQEWYdG64Ha58

Appendix B. List of knowledge domain questions used in Phase 4 validation

Item	Question
K1	It is mandatory for medicines in Malaysia to undergo registration with the Ministry of Health Malaysia (MOH). ○ True ○ False
K2	NPRA is the agency responsible for the registration of medicines in Malaysia. ○ True ○ False
K3	All registered medicines in Malaysia have registration numbers. ○ True ○ False
K4	Medicine registration numbers in Malaysia begin with 'MAL'. ○ True ○ False
K5	Hologram Security Label is one of the characteristics of a registered medicine.  ○ True ○ False
K6	SIRIM certification label is one of the characteristics of a registered medicine.  ○ True ○ False
K7	JAKIM Halal label is one of the characteristics of a registered medicine.  ○ True ○ False
K8	MAL registration numbers that end with the letter A (eg MAL12345678A) refer to Controlled Medicines. ○ True ○ False
K9	MAL registration numbers that end with the letter B (eg MAL12345678B) refer to Group B Controlled Medicines. ○ True ○ False
K10	MAL registration numbers that end with the letter X (eg MAL12345678X) refer to Non-Scheduled Poisons or Over-The-Counter (OTC) Medicines. ○ True ○ False
K11	MAL registration numbers that end with the letter T (eg MAL12345678T) refer to Traditional Medicines. ○ True ○ False
K12	MAL registration numbers that end with the letter N (eg MAL12345678N) refer to Health Supplements. ○ True ○ False
K13	The registration status of a medicine in Malaysia can be checked through : a. the NPRA Product Status mobile application, and b. the websites www.npra.gov.my or www.pharmacy.gov.my ○ True ○ False

Appendix B. Continued

Item	Question
K14	Which one of the Hologram Security Labels is mandatory on medicine packaging : Label A:  Label B:  ○ Label A ○ Label B
K15	Which one of the applications can be used to verify the authenticity of Hologram Security Labels : FarmaCheckerTM:  MIMS Malaysia:  ○ FarmaCheckerTM ○ MIMS Malaysia
K16	The registration number of Pil Chi Kit Teck Aun is MAL19950914T. This medicine is a traditional medicine.  ○ True ○ False
K17	All creams used to treat skin diseases are required to be registered with MOH. ○ True ○ False
K18	Medicated oils for external use are required to be registered with MOH.  ○ True ○ False
K19	Traditional medicines in the forms of liquids, capsules, tablets or others are required to be registered with MOH. ○ True ○ False

Appendix B. Continued

Item	Question
K20	Registered medicines can be obtained at registered clinics and licensed pharmacies. ○ True ○ False
K21	Registered medicines can be obtained at grocery stores. ○ True ○ False
K22	Non-Scheduled Poisons or Over-The-Counter (OTC) Medicines (eg MAL12345678X) can be obtained from grocery stores. ○ True ○ False
K23	Traditional medicines (eg MAL12345678T) can be obtained from grocery stores. ○ True ○ False
K24	Health supplements (eg MAL12345678N) can be obtained from grocery stores. ○ True ○ False
K25	Controlled medicines (eg MAL12345678A) can be obtained from grocery stores. ○ True ○ False
K26	Controlled medicines (eg MAL12345678A) can be obtained from licensed pharmacies. ○ True ○ False
K27	Controlled medicines (eg MAL12345678A) can be obtained from registered clinics. ○ True ○ False
K28	Supplying/selling unregistered medicines is punishable by law. ○ True ○ False

Appendix C. Revisions suggested by the language experts

Item	Language	Original version	Revised version
Q16	English	Affixing the following hologram security labels on medicine labels or boxes is compulsory:	Affixing the following hologram security labels on medicine labels or boxes is mandatory:
Q20	Malay	Minyak sapuan kegunaan luaran untuk tujuan perubatan perlu berdaftar dengan KKM.	Minyak sapuan luar yang digunakan untuk tujuan perubatan perlu berdaftar dengan KKM.

Appendix D. Modifications to knowledge items based on expert panel review

Original code	Original item	Action taken	Final code	Final item
Q1	Medicines in Malaysia are required to be registered with the Ministry of Health Malaysia (MOH).	Rephrased	K1	It is mandatory for medicines in Malaysia to undergo registration with the Ministry of Health Malaysia (MOH).
Q2	The agency responsible for registering medicines in Malaysia is NPRA (National Pharmaceutical Regulatory Agency).	Rephrased	K2	NPRA is the agency responsible for the registration of medicines in Malaysia.
Q3	Medicines registered in Malaysia must comply with the Drug Registration Guidance Document issued by NPRA.	Removed – Irrelevant for healthcare personnel	-	-
Q4	All registered medicines in Malaysia have registration numbers.	Retained	K3	All registered medicines in Malaysia have registration numbers.
Q5	Medicine registration numbers begin with 'MAL'.	Retained	K4	Medicine registration numbers in Malaysia begin with 'MAL'.
Q6	MAL registration number is one of the characteristics of a registered medicine.	Removed – Redundant with K3 and K4	-	-
Q7	Hologram security label is one of the characteristics of a registered medicine.	Retained	K5	Hologram Security Label is one of the characteristics of a registered medicine.
Q8	SIRIM certification label is one of the characteristics of a registered medicine.	Retained	K6	SIRIM certification label is one of the characteristics of a registered medicine.
Q9	JAKIM Halal label is one of the characteristics of a registered medicine.	Retained	K7	JAKIM Halal label is one of the characteristics of a registered medicine.
Q10	MAL registration numbers that end with the letter A (eg MAL12345678A) refer to Controlled Medicines.	Retained	K8	MAL registration numbers that end with the letter A (eg **MAL**12345678**A**) refer to Controlled Medicines.
Q11	MAL registration numbers that end with the letter B (eg MAL12345678B) refer to Group B Controlled Medicines.	Retained	K9	MAL registration numbers that end with the letter B (eg **MAL**12345678**B**) refer to Group B Controlled Medicines.
Q12	MAL registration numbers that end with the letter X (eg MAL12345678X) refer to Non-Scheduled Poisons or Over-The-Counter (OTC) Medicines.	Retained	K10	MAL registration numbers that end with the letter X (eg **MAL**12345678**X**) refer to Non-Scheduled Poisons or Over-The-Counter (OTC) Medicines.
Q13	MAL registration numbers that end with the letter T (eg MAL12345678T) refer to Traditional Medicines.	Retained	K11	MAL registration numbers that end with the letter T (eg **MAL**12345678**T**) refer to Traditional Medicines.
Q14	MAL registration numbers that end with the letter N (eg MAL12345678N) refer to Health Supplements.	Retained	K12	MAL registration numbers that end with the letter N (eg **MAL**12345678**N**) refer to Health Supplements.
Q15	The registration status of a medicine can be checked through 2 ways, which are: a. the NPRA Product Status mobile application, and b. the websites www.npra.gov.my or www.pharmacy.gov.my	Rephrased	K13	The registration status of a medicine in Malaysia can be checked through: a. the NPRA Product Status mobile application, and b. the websites www.npra.gov.my or www.pharmacy.gov.my

Appendix D. Continued

Original code	Original item	Action taken	Final code	Final item
Q16	Affixing the following hologram security labels on medicine labels or boxes is mandatory: Label A:  Label B:  	Rephrased	K14	Which one of the Hologram Security Labels is mandatory on medicine packaging: Label A:  Label B: 
Q17	The authenticity of the hologram security label FarmaTag can be checked through these mobile applications: • NPRA Product Status • MyUBAT • FarmaChecker™ • MIMS Malaysia	Options reduced	K15	Which one of the applications can be used to verify the authenticity of Hologram Security Labels : • FarmaChecker™ • MIMS Malaysia
Q18	The registration number of Pil Chi Kit Teck Aun is MAL19950914T. This medicine is a traditional medicine.	Retained	K16	The registration number of Pil Chi Kit Teck Aun is MAL19950914T. This medicine is a traditional medicine.
Q19	Creams used to treat skin diseases are required to be registered with MOH.	Rephrased to include “All”	K17	All creams used to treat skin diseases are required to be registered with MOH.
Q20	Medicated oils for external use are required to be registered with MOH.	Retained	K18	Medicated oils for external use are required to be registered with MOH.
Q21	Medicines in the form of tablets or capsules made from traditional herbs (e.g. jamu) are required to be registered with MOH.	Retained	K19	Medicines in the form of tablets or capsules made from traditional herbs (e.g. jamu) are required to be registered with MOH.
Q22	Registered medicines can ONLY be obtained at registered clinics and licensed pharmacies.	“ONLY” removed	K20	Registered medicines can be obtained at registered clinics and licensed pharmacies.
Q23	Registered medicines can be obtained at grocery stores.	Retained	K21	Registered medicines can be obtained at grocery stores.
Q24	Non-Scheduled Poisons or Over-The-Counter (OTC) Medicines (eg MAL12345678X) can be obtained from grocery stores.	Retained	K22	Non-Scheduled Poisons or Over-The-Counter (OTC) Medicines (eg MAL12345678X) can be obtained from grocery stores.
Q25	Traditional medicines (eg MAL12345678T) can be obtained from grocery stores.	Retained	K23	Traditional medicines (eg MAL12345678T) can be obtained from grocery stores.
Q26	Health supplements (eg MAL12345678N) can be obtained from grocery stores.	Retained	K24	Health supplements (eg MAL12345678N) can be obtained from grocery stores.
Q27	Controlled medicines (eg MAL12345678A) can be obtained from grocery stores.	Retained	K25	Controlled medicines (eg MAL12345678A) can be obtained from grocery stores.
Q28	Controlled medicines (eg MAL12345678A) can be obtained from licensed pharmacies.	Retained	K26	Controlled medicines (eg MAL12345678A) can be obtained from licensed pharmacies.
Q29	Controlled medicines (eg MAL12345678A) can be obtained from registered clinics.	Retained	K27	Controlled medicines (eg MAL12345678A) can be obtained from registered clinics.
Q30	Individuals and/or companies found to own or sell unregistered medicines by the Ministry of Health of Malaysia can be prosecuted in court.	Rephrased	K28	Supplying/selling unregistered medicines is punishable by law.

Appendix E. Reworded item based on face validity feedback

Item	Original version	Revised version	Reason for change
K19	Medicines in the form of tablets or capsules made from traditional herbs (e.g. *jamu*) are required to be registered with MOH.	Traditional medicines in the forms of liquids, capsules, tablets or others are required to be registered with MOH.	Broadened the description and simplified phrasing to enhance clarity and inclusiveness across dosage forms.