Interprof. J. Health Sci. 2020, 18(1): 29-36.
ISSN (online) 2672-9423 ISSN (print) 2672-9628

DEVELOPING INDONESIAN GUIDELINES ON CLAIMS FOR HEALTH SUPPLEMENTS FOR THE ELDERLY BASED ON ASEAN GUIDELINES USING THE DELPHI TECHNIQUE

Erni Rahmawati[1,*], Thanapat Songsak[1], Yupin Lawanprasert[1], Purwantyastuti[2]

[1]College of Pharmacy, Rangsit University, Pathum Thani 12000, Thailand
[2]Faculty of Medicine, University of Indonesia, Indonesia

*Corresponding author: E-mail: rahmawatierni2014@gmail.com
Received 20 August 2019; Revised 25 September 2020; Accepted 16 October 2020

Abstract: In Indonesia, specific regulation on health supplement claims is yet to be developed. Clear guidance is needed for Health Supplement (HS) registrants who have registered their product to the Indonesian National Agency for Drug and Food Control. Regarding the content of new standards or regulations, the traditional way of pooling opinions is through face-to-face meetings. This study aims to develop the Indonesian Guidelines on Claims for Health Supplements for the Elderly (IGCHSE) using the Delphi technique. The method is employed to gain insight into the needs of all the stakeholders in order to obtain qualified and quantified guideline content. The main content of the IGCHSE is based on ASEAN guidelines on claims, which is in line with ASEAN harmonization of standard implementation. Some adaptations and modifications to the current Indonesia regulations, together with a review of international regulations on claims, have been used to enrich and expand the guideline content. The two-round Delphi technique process aimed to obtain consensus on the IGCHSE concept. Representatives from internal and external organizations worked together as an expert panel to develop and establish the guidelines. In the first round, the experts were given a structured questionnaire of items in the draft of guideline, interspersed with the ASEAN guidelines on claims. The list of items in the guideline concept was rated by the Delphi experts using a 5-point Likert scale. The feedback process allowed for and encouraged the Delphi experts to reassess their initial evaluation of the information provided in the previous version of the draft guidelines. This information was used to redevelop the second version. In the analysis, in rounds one and two the consensus data were calculated based on the median, inter-quartile range, quartile deviation, standard deviation and coefficient variation. In the two rounds of the Delphi panel, the median value was higher than 4, and the frequency of the 4 and 5 percentage values was higher than 50%, showing that the level of importance of the items was high. According to the level of consensus, the quartile deviation (QD) rate of the Round 2 Delphi panel was lower or equal to 0.5 ($QD \leq 0.5$), which means that all items achieved consensus. In conclusion, the IGCHSE concept reached consensus by using the two round Delphi techniques.

Keywords: Claim, Health supplement, Guideline, Development, Delphi technique

INTRODUCTION

In Indonesia, health supplement (HS) products are subject to pre-market approval, including of its claims and advertising. Claims refer to any messages that state, suggest or imply that a HS product makes a positive contribution to and benefits human health (ASEAN, 2014). Such claims on the link between consumption of the product and health benefits are made on product labels or in advertising. All aspects of HS labels and advertising contribute to the overall impression made by HS product claims. All information that is provided on labels or in advertising must be accurate, truthful and not misleading (NADFC, 2019)

At the moment, there are no specific regulations on such claims in Indonesia. Therefore, in light of ASEAN harmonization on the standard and quality of health supplements, including the regulation of claims, Indonesia needs to prepare regulations in line with ASEAN standards.

This study aims to develop the Indonesian Guidelines on Claims for Health Supplements for the Elderly (IGCHSE) based on ASEAN guidelines on claims, using the Delphi consensus technique. The purpose of the guidelines is to help HS registrants to comply with the requirements on HS claims and on how to prepare the substantiation documents more specifically and in more detail related to applications for HS products for the elderly.

The HS for elderly group was chosen due to its potential as an HS segment market. It is predicted that the percentage of the elderly population in Indonesia will increase by 0.3 % every year and that the market for multivitamins for the elderly will also increase by 0.1 % every year (Indonesia Ministry of Health, 2014).

The study employed the Delphi technique, which has become an important data collection method, with a wide variety of applications and uses for researchers who wish to gather information on a topic. The technique uses a particular method to obtain the constructs and content items when developing guidelines. It is an iterative process, which aims to collect a wide range of opinions from a group of experts (Ab Latif et al., 2017). Agreement on related items is based on consensus. The Delphi technique has been applied in previous studies, such as ones on appraisal of the use of multivitamin/multi-mineral supplements; guidance development in clinical and healthcare practice; and the mapping of care plans and assessment in health education (Blumberg et al., 2018; (Ab Latif et al., 2017; Msibi et al, 2018).

MATERIALS AND METHODS

The main of study employed the Delphi panel technique. Prior to the expert panel convening, activities were conducted to establish the problems regarding HS claims.

The first step of the GCHSE development was identification of the problems regarding claims for HS for the elderly, for which a focus group discussion (FGD) of HS registrant was conducted and information from the public including consumer and health professionals for which in depth interview were collected.

The FGD involved ten HS registrants who had had problems regarding registration of product claims. They joined together to share their experiences and opinions regarding HS claims. The public informants who involved in depth interview were fourteen comprise of consumers, health professionals, and academicians.

The content of the guidelines on claims was developed using the Delphi technique. In the consensus procedure, the selection of Delphi experts is very important, as the technique relies on a panel of experts who can reach a reliable consensus. Experts are individuals with relevant knowledge and experience of a particular topic (Cantrill et al., 1996). The selection of experts in this case was based on the objective and the background of study, and their practices and skills.

The panel comprised experts from internal and external NADFC organizations, including two representatives from HS registrant, four experts from different NADFC divisions, three experts from academia, one expert from healthcare providers and one representative from the Indonesian Ministry of Health. With their different experience, they were able to make suggestions on the questions raised by the researcher. 11 (eleven) experts were therefore invited to join the Delphi procedure, which was considered an adequate number (Kamonpatana et al., 2015). According to the references, the number of experts of 9 (nine) to 11 (eleven) experts in a Delphi study yield that the reduction of error is 0.04 (Macmillan, 1971; Thapom, 2014).

The Delphi process can be continuously iterated until consensus has been achieved. In the technique, the experts give free comments related to the issues in question. The approach is

based on a structural process for collecting and eliciting knowledge from a group of experts by means of a series of questionnaires.

A literature review was conducted prior the first draft guidelines on claim development. A comparison table between current Indonesian regulations on claims and other international regulations and standards was used to explore the guideline content. In the first round, the experts were given a structured questionnaire regarding proposed guideline content, together with the ASEAN guidelines on claims for comparison.

A list of items in the draft guidelines on HS claims was provided to the Delphi experts. They were asked to rate the categorized responses in round 1 and round 2 on a scale of 1 to 5, with 1 being 'strongly disagree'', to 5 'strongly agree'. Between the two rounds, the experts were invited to discuss the results from round 1. The feedback process allowed and encouraged them to reevaluate their initial evaluation of the information provided in the previous version of the guidelines.

The outcome from the first round of the questionnaire was analyzed and became the basis for the second round. The outcome from this led to the final round. The objective of each round was to elucidate and extend on the issues, identify areas of agreement or disagreement, and to make assessments in order to reach consensus.

The second version was reformulated by the researcher based on the results from Delphi 1, which became Delphi Round 2, and the final, or third version, was again reformulated based on the outcomes from Delphi Round 2.

Expert consensus was reached if the assessment using the three measures combined for the 5-point Likert Scale found that: (i) 51% of the experts' opinions were in the category 'strongly agree' (between the values of 4 and 5 on the scale); (ii) the interquartile range (IQR) was below 1; and (iii) the standard deviation (SD) was below 1.5 (Giannarou and Zervas, 2014). A previous study determined that there was a high level of consensus and high level of importance if the quartile deviation (QD) was less than or equal to 0.5, and the median was 4 or above (Ab Latif et al., 2017).

In another study, expert consensus was assessed using the combined median (Md), mode (Mo) and inter-quartile range (IQR) measure. If the inter-quartile range value was equal to or less than 1.50, it meant that the opinions of the experts on that item were consistent. The item was selected for inclusion in the guidelines if the median (Md) was ≥3.50, the difference between the median and mode (Md-Mo) ≤1, and the inter-quartile range (IQR) was ≤1.50 (Thapom, 2014). Cronbach's alpha is a useful statistic for measuring the extent of consensus among panel members.

RESULTS AND DISCUSSION

The results of the FGD are presented in Table 1, which shows the main comments for and against the development of the guidelines on HS claims.

From the positive aspect, they commented that the guidelines were a way of improving compliance with claim regulations, and that they required good quality content and practice. Comments included:

"The guidelines are the good tool to develop the quality of claim determination. The implementation will be successful if HS registrants accept and put effort into applying the guidelines into practice".

"The guidelines will promote the registration process in order to run HS evaluation transparently, effectively and consistently."

On the other hand, some informants believed that the guidelines raised issues of impracticality, increased the financial burden, and were an additional measure in the registration process.

Table1. Main comments from the FGD meeting with the 10 HS registrants

For	
1	The guidelines are a tool for further development of national regulations on claims to enhance the efficacy and safety of HS products.
2	The guidelines will promote the transparency, effectiveness and consistency of the HS registration process.
3	The guidelines will encourage HS registrants to improve product innovation.
4	The guidelines will promote Indonesian HS product competitiveness in the ASEAN market.
5	The guidelines will achieve better consumer protection and satisfaction.
Against	
1	The guidelines should not include impractical items such as the registrant only provide evidence from study on constituent of product
2	The guidelines would impose a financial burden when preparing evidence from human studies to substantiate a specific claim.
3	The guidelines are perceived as an additional regulatory measure.
4	The guidelines are focused on the requirements for claims, rather than the obstacles faced by HS registrants regarding the substantiation documentation for the finished product.

In addition, the opinions from public informants were included, as follows: "Supplements are very important for the elderly because usually they are suffering from problems related to nutrition intake, decreased appetite, reduced metabolism and digestive system, toothless and illnesses related to age."

"HS are very important products in healthcare and have the potential to reduce medical health costs."

The majority of consumers knew that the government, namely the NADFC, controlled claims on labels and advertisements for HS products. They were satisfied with such control, except for HS advertising. They reported many exaggerated claims found in HS advertisements. One participant said:

"NADCF must strengthen HS control, especially for claims on the label and claims in brochures. Many endorsements are provided by retailers, by word of mouth or by multi-level marketing distribution."

Health professionals and academicians also reported overuse of HS because of claims in advertisements. They suggested that the government should strengthen HS advertising control as most was misleading, false or exaggerated.

Information from healthcare providers based on their observations of consumer buying behaviour included the fact that the majority of consumers already knew about and were familiar with the products they wanted to buy. The majority of consumers who purchased HS products for the elderly were female. The top five HS products bought were ones intended for general health and body endurance, maintenance of bone health, joint health, and the heart health, and help in relieving menopausal symptoms.

Guideline Development

The information from the problem identification was used to establish the objectives of the guidelines and example claims of products for the elderly. The two rounds of the Delphi panel experts had a 100% response rate. Development of the guideline content was made by experts through the two round Delphi Technique.

The first version of IGCHSE was formulated based on ASEAN guidelines on claims and a review of other nations' regulations regarding HS claims. In line with the Indonesian policy to adopt the result from ASEAN harmonization on standards and quality (ACCSQ), the ASEAN guidelines on claims for HS were used as the main reference for IGCHSE development. Adaption, modification, clarification or re-development was made in the IGCHSE development process.

Round 1 provided all the items which had an SD value below 1.5 and a percentage of agreement value frequency higher than 51%, although an interquartile range (IQR) value of more than 1 was found with seven items. In the first Delphi round, there were statements with a standard deviation of below 1.5 and/or 51% of the experts fell into the 'agree and strongly agree' (values 4 and 5) category, while the interquartile range was above 1, but consensus was still reached among the experts.

In Delphi round 1, some content and sections had to be modified and revised for moderation of consensus items, such as the introduction, objective, users, scope and application, and the case study on claims for HS products for the elderly. After the round 1, the researcher presented the results from the Delphi 1 round to the Delphi expert panel meeting. The outcomes from this meeting were as follows: some statements were added in the introduction section to emphasize the significance of the guidelines; the term 'user' in the user section was changed to 'target'; and scope was limited to the health benefits of product, and not to a product's name or product advertising.

The expert panel retained the public as third target users of the guidelines. The objectives of the guidelines were to serve as knowledge for decision making on health supplement use.

However, even though some appendixes had moderate consensus, the expert panel meeting suggested removing them from the guidelines, such as Appendix 1, General Claims for Vitamins and Minerals Classified 'Low Risk Products' and Appendix 2, List of Examples of Diseases/Conditions/Disorders Not Allowed for Health Supplements. Appendix 1 consists of the approved claim list for vitamins and minerals, but in fact each claim must be discussed individually before approval. In Appendix 2, it is not necessary to present the list in the guidelines because the intended use of HS is not for the prevention or treatment of any kind of disease. Only Appendix 3 was retained in the guidelines. Appendices 4, 5 and 6 were simplified and merged into one appendix, Examples of Claims and Claim Substantiation of HS products for the elderly.

The main comments and suggestions from the representatives of the HS registrants, and from the technical experts from the Indonesian HS Companies Association (APSKI), were summarized as follows:

"The supporting data to substantiate HS claim must be clear. For an HS product for which nutritional claims are made based on vitamins and/or minerals, it is recommended that they contain a minimum of 15% (Nutrient Reference Value) per daily dose of the vitamin and/or mineral to qualify it as a source of either of them, or as determined by the regulatory authorities." They insisted that the evidence to substantiate the claim must be full adopted from ASEAN guidelines on claim and claim substantiation for HS, including scientific opinion from scientific organizations and regulatory authorities.

For evaluation, they considered adding a new benefit of product for new product. They also proposed the necessity to open other appropriate system for a new product constituent, not only evidence to substantiate the claim from the finished product, but also from each active ingredient of the product's composition. They asked for some clarification of certain terminology and statements and suggested an explanation of these in detail. For the wording and language of claims, they proposed adding an example claim for disease prevention as a part of disease risk reduction claims.

They asked consideration to allow making a claim on the product label, such as Products have had a GMP certificate, have passed clinical study. They also asked for clarification on prohibited claims in HS, such as statements exploiting fear or nervousness or claiming "energy generation."

They commented that the guideline content should be clear and practical for HS registrants:

"There were many difficult items for present practice, such as the clinical trial data to substantiate a new claim".

They proposed some alternative options and revisions of impractical items and thought that these items should be revised to make them feasible and suitable for the current situation. Based on the results of round 1 and after the expert panel meeting, the researcher proposed the second IGCHSE version.

Results of the second round of the Delphi expert panel

The main section and the claim principles and substantiation section of the first and second versions were basically the same. There were some suggestions and minor changes regarding evidence from human study to substantiate a claim and the item 'Wording and Language' with regard to the examples of prohibited and misleading claims.

After Delphi 2, the data showed much more agreement. It was revealed that 63 % of items showed a high level of consensus or agreement in round 1, which increased to 100 % in round 2, as shown in Table 2. Following these results, the reliability analysis of the guidelines displayed a high confidence level. Cronbach's alpha was found to be 0.96 and 0.91 in rounds 1 and 2 respectively.

Table 2. Delphi results on the importance and level of consensus

Item	[1]Md	[2]IQR	[3]QD	Mode	[4]Ave	[5]Freq	[6]SD	[7]CV
Round 1								
I. Introduction (four sub items)	4	1.5	0.75	5	4.0	72.73	1.18	0.30
II. Objective (four sub items)	4	1.5	0.75	5	4.0	72.73	1.18	0.30
III. Users (three sub items)	4	1.5	0.75	5	3.6	54.55	1.12	0.31
IV. Scope and Application (two sub items)	4	1.5	0.75	5	3.9	72.73	1.14	0.29
V. Safety Consideration on the Population at Risk (one sub item)	4	1	0.5	4	3.8	72.73	1.08	0.28
VI. Principles of Claim (14 sub items)	4	1	0.5	5	4.2	81.82	0.98	0.23
VII. Guidance on Claim Substantiation (55 sub items)	4	1	0.5	4	4.1	81.82	0.94	0.23
VIII. Wording and Language (ten sub items)	4	1	0.5	4	4.1	81.82	0.94	0.23
IX. Case study of claim for HS product for the elderly (ten sub items)	4	2	1	5	3.9	63.64	3.9	0.27
X. Evaluation (11 sub items)	4	1	0.5	4	4.1	81.82	4.1	0.23
XI. Conclusion (one sub item)	4	0.5	0.25	4	4.0	81.82	4.0	0.22
XII. References (15 sub items)	4	1.5	0.75	5	3.9	72.73	3.9	0.29
XIII. Operational Definition (12 sub items)	4	1.5	0.75	5	3.9	72.73	1.14	0.29

Table 2. Delphi results on the importance and level of consensus (Continued)

Item	[1]Md	[2]IQR	[3]QD	Mode	[4]Ave	[5]Freq	[6]SD	[7]CV
Appendix 1. General Claim for Vitamins and Minerals Classified as "Low Risk Products" (one sub item)	4	0.5	0.25	4	4.0	81.82	0.89	0.22
Appendix 2. List of Examples of Diseases/ Conditions/ Disorders Not Allowed for HS (one sub item)	4	1	0.5	4	4.1	81.82	0.94	0.23
Appendix 3. Source of supporting documents from published references (one sub item)	4	1	0.5	4	4.1	81.82	0.94	0.23
Appendix 4. Example of general claim for HS for the elderly (one sub item)	4	1	0.5	4	4.1	81.82	0.94	0.23
Appendix 5. Example of medium claim for HS for the elderly (one sub item)	4	1	0.5	4	4.1	81.82	0.94	0.23
Appendix 6. Example of high claim for HS for the elderly (one sub item)	4	1	0.5	4	4.1	81.82	0.94	0.23
Cronbach's alpha value= 0.96, N items = 19, N sub items=115								
Round 2								
I. Introduction (four sub items)	4	1	0.5	4	4.27	90.91	0.65	0.15
II. Objective (four sub items)	4	1	0.5	4	4.27	90.91	0.65	0.15
III. Targets (three sub items)	4	0.5	0.25	4	4.18	90.91	0.60	0.14
IV. Operational Definition (12 sub items)	4	0.5	0.25	4	4.18	90.91	0.60	0.14
V. Scope and Application (two sub items)	4	1	0.5	4	4.36	100.0	0.50	0.12
VI. Principles of Claim (36 sub items)	4	1	0.5	4	4.09	81.82	0.94	0.23
VII. Guidance for Claim substantiation (26 sub items)	4	1	0.5	4	4.09	81.82	0.94	0.23
VIII. Wording and Language (eight sub items)	4	1	0.5	4	4.09	81.82	0.75	0.18
IX Evaluation (11 sub items)	4	1	0.5	4	4.18	90.91	0.65	0.15
X. Conclusion (one sub item)	4	1	0.5	4	4.27	81.82	0.94	0.23
XI. References (19 sub items)	4	1	0.5	4	4.27	90.91	0.65	0.15
Appendix 1. Source of published references as supporting data for HS claims (one sub item)	4	1	0.5	4	4.27	90.91	0.65	0.15
Appendix 2. Decision tree on the evidence required to support the different types of HS claim (one sub item)	4	1	0.5	4	4.09	81.82	0.94	0.23
Appendix 3. Examples of Claims and Claim Substantiation of HS Products for the Elderly (three sub items)	4	0.5	0.25	4	4.18	90.91	0.60	0.14
Cronbach's alpha value= 0.91, N items = 14, N sub stems=93								

[1]MD: Median; [2]IQR: interquartile range; [3]QD: quartile deviation; [4] Ave: Average;
[5]Freq: % of total 4&5 value; [6]SD: standard deviation; [7]CV: Coefficient Variation

The result of study provides a structure of IGCHSE comprising of introduction, objective, targets, operational definition, scope and application, principles of claim, guidance of claim substantiation, types of claim, claim substantiation and principle of claim substantiation, wording and language, evaluation, conclusion, references, and appendices. The summary of IGCHSE is summarized as follows: this guideline to obtain similarities of understanding for registrant and regulator in the Health Supplement product for elderly in registration process related to product claims in accordance with the type and level of evidence to support the product claims. These guidelines seek to exemplify the evidence of claim required for registration. The guidelines apply to new claims and adequate evidence to be submitted in original and subsequent applications for marketing authorization of a new HS product for elderly. This guideline also provides guidance on making unbiased and truthful HS claims,

in order to protect the consumers from misleading claims so they will be able to make informed choices in using HS for elderly.

CONCLUSION

In conclusion, the Indonesian Guidelines on Claims for Health Supplements for the Elderly has reached consensus after two rounds of the Delphi expert panel and the involvement of all stakeholders in the expert panel reached the good quality of guideline. The Delphi technique is an alternative method of obtaining consensus in regulation development in Indonesia in the context of health supplement claims.

REFERENCES

Ab Latif R, Dahlan A, Ab Mulud Z, Mat Nor MZ. 2017. The Delphi Technique as a Method to Obtain Consensus in Health Care Education Research. *Educ. Med. J.* 9(3), 89–102.

ASEAN. 2014. *Annex VII ASEAN Guidelines on Claims and Claims Substantiation for Health Supplement* Retrieved from https://asean.org/wp-content/uploads/2017/09/ ASEAN-Guidelines-on-Claims-Claims-Substantiation-HS-V2.0-with-discla....pdf

Blumberg JB, Cena H, Barr SI, Biesalski HK, Dagach RU, Delaney B, *et al*. 2018. The Use of Multivitamin/Multimineral Supplements: A Modified Delphi Consensus Panel Report. *Clin. Ther.* 40(4), 640–657.

Cantrill JA, Sibbald B, Buetow S. 1996. The Delphi and nominal group techniques in health services research. *Int. J. Pharm. Pract.* 4, 67-74.

Giannarou L, Zervas E. 2014. Using Delphi technique to build consensus in practice. *Int. J. Business Sci. Appl. Management.* 9(2), 65–82.

Indonesia Ministry of Health. (2014). *Situation and Analysis for Elderly*. Retrieved from http://www.depkes.go.id/resources/download/pusdatin/infodatin/infodatin lansia 2016.pdf

Kamonpatana K, Anuntavoranich P, Varodompun J, Sunakorn P, Thaitakoo D, Wattanapreechanon K. 2015. Modified Fuzzy Delphi Method to select decision variables for vertical farming in Thailand. *Kasetsart J. Soc. Sci.* 36(3), 554–567.

Macmillan TT. 1971.The Delphi Techniques. Paper presented at the annual meeting of the California Junior Colleges Associations Committee on Research and Development, Monterey, California May 3-5, 1971

Msibi PN, Mogale R, De Waal M, Ngcobo N. 2018. Using e-Delphi to formulate and appraise the guidelines for women's health concerns at a coal mine: A case study. *Curationis*. 41(1), 1–6.

National Agency for Drug and Food Control. 2019. Decree of the Head of National Agency for Drug and Food Control Number. HK.00.05.41.3644 regarding Provision of Food Supplement Control.

Thapom S. 2014. Development of Thai Version Assessment tool for blood service unit by EFQM excellent model (Unpublished Master's thesis). Mahidol University, Bangkok.