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Brief Report

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Upgrading of Quality Control for Herbal Medicine Use in South Korea by Introducing an Accreditation System: a brief report

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Objectives: This study aimed to present a government-led accreditation system for upgrading the quality control of herbal medicine by introducing the process and evaluation standard of external herbal dispensaries (EHDs) of traditional Korean medicine (TKM) clinics in South Korea 2018 to refer to other countries where herbal medicine were used similarly in Korea.
Development Process: We organized an EHD accreditation committee for the establishment of an accreditation system. The committee consisted of 9 experts: an official of the Ministry of Health and Welfare (MoHW), a professor expert of TKM, a good manufacturing practice expert, a hazard analysis and critical control point expert, and an accreditation system expert. After 3 meetings, a draft of the evaluation standard and evaluation system was established in 2017. Based on the draft, a pilot test was conducted to determine the applicability of the evaluation standards in 2017. Two additional meeting was held to confirm the accreditation standards and was finalized in 2018.
Results: The evaluation standard for EHDs was developed. In the case of herbal medicine EHDs, the evaluation standard consisted of 9 evaluation categories, 25 evaluation parts, and 81 evaluation items were developed. The results of the evaluation of the pilot tests are as follows, and the results show that there is a deviation between the EHDs.
Conclusion: As a world's first, Korea MoHW successfully launched the accreditation system for upgrading the quality control system of herbal medicine not approved by Korea's Ministry of Food and Drug Safety in 2018. Our report hope to provide a good reference to other countries where having similar herbal medicine system in South Korea hoping to make better quality control of herbal medicines.

Keywords: herbal medicine, accreditation system, quality control, external herbal dispensaries, traditional Korean medicine

INTRODUCTION

There has been a remarkable and rapid increase in the use of herbal medicines worldwide. Herbal medicine formulations have been used for thousands of years in East Asian countries, particularly in China, Korea, and Japan [1]. The healthcare systems of many nations have incorporated the application of herbal medicines in treating various health problems. An estimated 80% of the global population uses herbal medicines for primary healthcare [2]. In 2017, the global market of herbal medicinal products was estimated at 59.45 billion USD, and the market is expected to grow steadily [3]. As the consumption of herbal medicinal products increases globally, the question of their safety has become paramount. Most herbal medicines need to be researched scientifically, and their safety and efficacy established, without ignoring the insights garnered from their traditional use over the years. Therefore, it is necessary to provide adequate information about the risks of herbal medicines for the public and ensure the safety of these products.

Usually, the Ministry of Food and Drug Safety (MFDS) of

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each country is responsible for the quality control (including safety and efficacy) of herbal medicines [4]. The standards for quality control of herbal medicines vary across countries, but in general, they are focused on ensuring safety [4]. As such, quality control of herbal medicines not licensed by MFDS is important and remains challenging for countries that produce and supply these products.

China and South Korea have traditionally had a high demand for herbal medicines. In both countries, these medicines are manufactured by pharmaceutical companies, and in Korea, they are supplied to the public through traditional Korean Medicine (TKM) clinics [5]. Unlicensed Chinese medicines are prepared in herbal dispensaries and supplied to traditional medicine institutions or clinics [6]. Usually, herbal medicine formulations are prepared in the external herbal dispensaries (EHD) of TKM clinics. Practitioners of TKM send their prescriptions to EHDs for the preparation of these medicines. There is a total of 98 EHDs in Korea, of which 32 are in Seoul.

Korea's Ministry of Health and Welfare (MoHW) has announced the introduction of an accreditation system for the EHDs of TKM clinics. Accreditation is the process of evaluation of an applicant by a formal accrediting institution to determine if the applicant conforms to a set of pre-defined standards [7]. Accreditation has often been recommended to improve quality across diverse fields [8].

This article presents the process of developing an accreditation system for EHDs in Korea. In addition, we conducted a pilot study to determine the applicability of the developed system. A further purpose was to provide a reference for controlling the quality of herbal medicines in countries that have a traditional medicine system. To the best of our knowledge, this is the first study to establish an accreditation system for EHDs to manage the quality of herbal medicines licensed by Korea's MoHW but not by MFDS.

Table 1. Main contents of expert consultation

Meeting	Key discussions or decisions
1st meeting	The current standards of Medical Law Enforcement are based on all minimum standards for herbal dispensaries of TKM clinics. New standards to be applied to large-sized herbal dispensaries are required. The standards for H-EHDs, which are EHDs that prepare herbal medicines in such forms as pill, powder, tablet, decoction, and capsule.
2nd meeting	Discussion and establishment of H-EHD certification standards - Standards that are difficult to introduce in the current situation of EHD (e.g. installation of air conditioning equipment, 24-hour recording system, and sensory test facility for herbs (raw materials)) were excluded. - Standards for preparing herbal medicine formulations, such as paste, pill, powder, and tablet, were included.
3rd meeting	Selection of evaluation standards for the pilot test - Eight evaluation categories, 21 evaluation parts, and 67 evaluation items were selected for the pilot test of E-EHD certification standards.
Pilot test (2017.11.16.-2017.12.14.)	
4th meeting	Discussion and establishment of H-EHD certification standards reflecting the results of the pilot test - One evaluation category (3. Management and organization operation) and four evaluation parts (3.1 Organization, 3.2 Business management, 3.3 Sessions operation, 8.2 Preparation in advance), and 14 evaluation items were newly established. - Considering that EHDs are attached facilities established by TKM clinics, category '3. Management and organization operation', including eight evaluation items, was established. - Considering that EHDs are preparation facilities, and not manufacturing facilities, evaluation part '8.2 Preparation in advance', including two evaluation items, was established. - The EHD committee additionally introduced four items for hygiene management of facilities (e.g. sealing corners of EHD entrances) and employees (e.g. management of work clothes).
5th meeting	Determination of evaluation standard for EHD accreditation - Nine evaluation categories, 25 evaluation parts, and 81 evaluation items were decided by the consensus of the EHD accreditation committee.

EHD, External Herbal Dispensaries of traditional Korean medicine clinics; H-EHD, External Herbal Dispensaries of traditional Korean medicine clinics preparing herbal medicine; TKM, Traditional Korean Medicine.

DEVELOPMENT PROCESS

1. The process of developing standards for EHDs

The National Institute for Korean Medicine Development (NIKOM) has developed the draft certification standards concerning domestic food and drugs, called the certification standards for EHDs preparing herbal medicines (H-EHDs).

The draft indicators of the H-EHD standards were developed referring to the Hazard Analysis and Critical Control Points, enforcement regulations of the Food Sanitation Act, and rules on the safety of medicines and other products.

To examine the validity of the certification standards developed by NIKOM, the EHD accreditation committee met four times to develop the certification indicators. After the pilot test, four additional meetings were held to confirm the accreditation standards. Table 1 lists the main points discussed by the committee. Finally, we developed the certification standards for H-EHDs. The accreditation standard for H-EHDs comprised 9 evaluation categories, 25 evaluation parts, and 81 evaluation items.

2. Pilot testing

The pilot evaluation (Table 2) was conducted to determine the applicability of the evaluation index before introducing the EHD accreditation system. To select the pilot test subjects, we posted the announcement of EHD recruitment on the NIKOM homepage from September 28 to November 3, 2017. Applications were submitted according to the type of EHD, and a total

Table 2. Pilot Evaluation standard of external herbal dispensaries of traditional Korean medicine clinics preparing herbal medicine (H-EHD)

Evaluation categories	Evaluation part	Items
1. Herbal Dispensaries Facilities	1.1 Common Facilities of Herbal Dispensaries	5
	1.2 Partitioning	4
	1.3 Storage Facilities	1
	1.4 Drainage Facilities	1
	1.5 Preparation Supporting Facilities	1
	1.6 Prevention of Insect and Heat	1
2. Herbal Dispensaries Management	2.1 Facility (Device) Management	2
	2.2 Hygiene Management of Herbal Dispensaries	4
3. Management and Organization Preparation	3.1 Organization	3
	3.2 Business Management	4
	3.3 Sessions Operation	1
4. Employee Management	4.1 Education	1
	4.2 Personal Hygiene Management	4
5. Document Management	5.1 Production of Documents	2
	5.2 Archiving and Disposing of Documents	1
6. Continuous Quality Control	6.1 Quality Management System	2
	6.2 Complaints Management	1
7. Herbal Medicine Management	7.1 Herbal Medicine Management	3
	7.2 Storage, Use, and Disposal of Herbal Medicine	4
8. Management of Preparation	8.1 Process Management	8
	8.2 Preparation in Advance	2
	8.3 Checking the Preparation	3
9. Packaging Management	9.1 Management of Packaging Materials	1
	9.2 Packaging Operation Management	3
Total		67

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of 12 EHDs submitted applications. Among them, six H-EHDs were selected considering their area, size, and type. The pilot evaluation was conducted from November 16 to December 14, 2017. The main points discussed by the EHD accreditation committee to determine the evaluation index based on the pilot test were the same as those covered in the fifth meeting of the committee and are listed in Table 1.

RESULTS

1. Results of pilot testing

The pilot test showed wide differences in scores obtained by the EHDs (Table 3). Of the six EHDs, four EHDs scored 75% or higher, while the remaining two scored 53% and 6%, respectively. Most EHDs scored low on 'dispensaries management' and high on 'document management.' A brief explanation of the 14 items added after the pilot test is presented in Table 1 (see the fourth meeting).

2. Standards of evaluation for EHDs

Regular components for 'herbal medicine' certification comprise 9 standards, 25 categories, and 81 items (Table 4). The nine standards include 'herbal dispensary facilities,' 'herbal dispensaries management,' 'management and organization operation,' 'employee management,' 'document management,' 'continuous quality control,' 'herbal medicine management,' 'management of preparation,' and 'pavement management.' More information on individual evaluation standards is available in the press release, "Introduction of EHDs of TKM Clinics," issued by the MoHW [9]. The English version of the final evaluation items is provided as a Supplementary file.

DISCUSSION

1. Implementation of the accreditation system

In Korea, TKM clinics obtain herbal medicines in one of three ways. The first method is to obtain herbal medicines licensed and supplied by Korea's MFDS. There are three types of herbal medicines licensed by Korea's MFDS — powders, soft extracts, and pills [10]. The second way is to obtain herbal medicines prepared in TKM institutions. Herbal medicines obtained in this manner are mostly in the form of decoctions. The third method involves receiving herbal medicines prepared in EHDs according to the prescription of TKM clinics. EHDs are responsible for producing and supplying pills, powders, and medicines that are difficult to prepare in the TKM institutions themselves [11]. As per the MoHW Report on Consumption of TKM in 2017, the average annual number of prescriptions for medicinal herbs licensed by Korea's MFDS was 1,380, whereas that of herbal medicine prescriptions not licensed by Korea's MFDS was 930 [12]. Thus, both licensed and uncertified herbal medicines are supplied at a similar scale. To ensure that the supplied herbal medicines are safe, it is necessary to manage uncertified herbal medicines. As such, the MoHW announced the implementation of an accreditation system for EHDs based

Table 3. The results of the pilot tests

Evaluation area	H-EHDs					
	A	B	C	D	E	F
1. Dispensaries Facilities	1/13 (7.7%)	13/13 (100.0%)	13/13 (100.0%)	9/13 (69.2%)	8/13 (61.5%)	12/13 (92.3%)
2. Dispensaries Management	1/6 (1.7%)	6/6 (100.0%)	3/6 (50.0%)	4/7 (57.1%)	1/7 (14.3%)	4/7 (57.1%)
3. Business and Organization Management	1/8 (12.5%)	6/8 (75.0%)	6/8 (75.0%)	8/8 (100.0%)	5/8 (62.5%)	8/8 (100.0%)
4. Employee Management	0/5 (0.0%)	5/5 (100.0%)	2/5 (40.0%)	3/5 (60.0%)	3/5 (60.0%)	5/5 (100.0%)
5. Document Management	0/7 (0.0%)	7/7 (100.0%)	5/7 (71.4%)	6/7 (85.7%)	4/7 (57.1%)	4/7 (57.1%)
6. Continuous Quality Management	0/3 (0.0%)	3/3 (100.0%)	1/3 (33.3%)	2/3 (66.7%)	1/3 (33.3%)	3/3 (100.0%)
7. Raw Medicinal Herbs Management	1/7 (14.3%)	7/7 (100.0%)	7/7 (100.0%)	7/7 (100.0%)	4/7 (57.1%)	7/7 (14.3%)
8. Compounding Management	0/13 (0.0%)	13/13 (100.0%)	9/11 (81.8%)	8/12 (66.7%)	7/11 (63.6%)	11/12 (91.7%)
9. Packing Management	0/4 (0.0%)	4/4 (100.0%)	2/4 (50.0%)	3/4 (75.0%)	2/4 (50.0%)	3/4 (75.0%)
Total (67* items)	4/66 (6.0%)	64/66 (97.0%)	48/64 (75.0%)	50/66 (75.8%)	35/65 (53.8%)	57/66 (86.4%)

*Out of a total 67 items, the evaluation was conducted excluding non-applicable items.

Table 4. Evaluation standard of external herbal dispensaries of traditional Korean medicine clinics preparing herbal medicine (H-EHD)

Evaluation Categories	Evaluation Part	Items
1. Herbal Dispensaries Facilities	1.1 Common Facilities of Herbal Dispensaries	5
	1.2 Partitioning	6
	1.3 Storage Facilities	2
	1.4 Drainage Facilities	1
	1.5 Preparation Supporting Facilities	2
	1.6 Prevention of Insect and Heat	2
2. Herbal Dispensaries Management	2.1 Facility (Device) Management	3
	2.2 Hygiene Management of Herbal Dispensaries	5
3. Management and Organization Preparation	3.1 Organization	3
	3.2 Business Management	4
	3.3 Sessions Operation	1
4. Employee Management	4.1 Education	2
	4.2 Personal Hygiene Management	5
	4.3 Infection Control	1
5. Document Management	5.1 Production of Documents	5
	5.2 Archiving and Disposing of Documents	2
6. Continuous Quality Control	6.1 Quality Management System	3
	6.2 Complaints Management	1
7. Herbal Medicine Management	7.1 Herbal Medicine Management	3
	7.2 Storage, Use, and Disposal of Herbal Medicine	5
8. Management of Preparation	8.1 Process Management	8
	8.2 Preparation in Advance	2
	8.3 Checking the Preparation	5
9. Packaging Management	9.1 Management of Packaging Materials	1
	9.2 Packaging Operation Management	4
Total		81

on specific evaluation standards starting in September 2018 to manage the quality of herbal medicines not licensed by Korea's MFDS [9].

2. The significance of introducing the accreditation system

The introduction of this evaluation and certification system is significant because of the following: i) quality control of herbal medicines usually entails standardization of their ingredients [1, 13-17]. In general, the external quality issues of these medicines pertain to three main aspects: cultivation, manufacturing, and circulation [18]. The objective of this certification system is not to standardize herbal medicine ingredients but to develop, evaluate, and certify the standards related to the modernization and management of EHDs and documents; in other words, this system aims to create an environment where safe herbal medicines can be prepared. This approach is new to the quality control of traditional herbal medicines.

ii) The introduction of a nationwide evaluation and certification system to guide the administration of herbal medicines represents a world first. Traditionally, herbal medicines have been used in private practice for thousands of years [19]. The management of these traditional medicines is a common concern and challenge for countries where they are used. The evaluation and certification system based on this proposed index is intended to manage traditional medicines at the government level rather than at the level of individual institutions and associations.

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3. Challenges and future directions of the evaluation and certification system

The EHD accreditation system is a 'voluntary certification system' that evaluates only the applying institutions. The certification is valid for three years, and quality control during the certification period is critical. During the certification period, follow-up management involving the following steps is required: (1) carrying out autonomous quality management through the submission of annual self-inspection reports; (2) confirming self-management through annual field inspection. For applicant institutions, it is necessary to carry out such follow-up management thoroughly and decide whether to maintain the certification.

There is also a need to develop educational and training programs related to operations. First, it is necessary to provide a training program that helps EHDs understand the accreditation system and certification standards. In this training, the agency undergoing evaluation should be able to identify specific preparations, such as photographs and documents that meet individual standards. Second, the EHD evaluator education program should incorporate: (1) a basic curriculum on the certification system and standards for the new EHD evaluator; (2) a professional curriculum on the precise points checked against the evaluation standards; and, (3) observation training for preparing field evaluation.

The management of medicine is under the purview of MFDS, whereas the management of EHDs that prepare herbal medicines is under the purview of MoHW. Therefore, the inspection and management of ingredients of herbal medicines are not reflected in the current EHD accreditation system because it is specific to Korea's MFDS.

Safety is a fundamental principle in medicine. As such, it is necessary to manage the quality and safety of herbal medicinal materials at every step, from production to consumption, through recording [20]. The management of herbal medicine ingredients should be introduced in EHD evaluation and certification. The management of the raw materials used in these medicines can ensure their safety in the future. In this regard, cooperation and discussion between MFDS and MoHW are needed.

CONCLUSION

The MoHW introduced an accreditation system for EHDs to ensure quality control of herbal medicines not licensed by the MFDS, a practice that is a first in the world. This accreditation system will enhance the quality of herbal medicines and facilitate the use of those not licensed by the MFDS. Under this certification and evaluation system, the facilities, documents, and preparation environment of EHDs where herbal medicines are prepared will be evaluated. In the future, the MoHW and FDA should work together to introduce a certification system that includes the inspection of the ingredients of herbal medicines to ensure their safety.

CONFLICTS OF INTEREST

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SUPPLEMENTARY MATERIALS

Supplementary data is available at https://doi.org/10.3831/KPI.2024.27.3.270.

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