

The role of Korea Pharmaceutical Information Service (KPIS) in patient safety

ABSTRACT

Many countries are committed to enhance patient safety in the public health domain by applying IT technology to pharmaceuticals and medical devices such as surgical instruments and implants. Korea is also engaged in this, having recently mandated the use of bar codes in pharmaceutical products. Safety, efficacy and adequacy in dispensing of pharmaceutical products must be ensured. Given its large impact on the society and the high level of expertise required, the state needs to develop an institutional mechanism to manage all phases of the product life cycle, including development, manufacturing, distribution, sales and dispensing.



By **Dr. Jeong**,
Korea Pharmaceutical
Information Service
Center

Introduction

In this paper, the conditions that necessitate pharmaceutical information management will be reviewed. Moreover, the role and functions of the Korea Pharmaceutical Information Service (KPIS) will be explained through its major activities including standardisation for information management, collection of finished pharmaceuticals information and management of pharmaceutical bar code label system, with checking detailed accounts for patient safety.

Benefits of pharmaceutical information management

Knowledge-information is deemed as a determining factor to competitiveness of a modern society. Currently, massive investments to build high value-added contents are made by countries that aspire to assume a leadership position in information society.

Informatisation in the pharmaceutical industry contributes to ensuring people's safe use of drugs, promoting the industry development and is likely to create more value than in other industries. The cost of pharmaceuticals takes up 30% of all health insurance benefits in Korea, a country with universal Healthcare coverage. Pharmaceutical information management is also emerging as an important issue because it contributes to fiscally sound operations in medical insurance.

If a country's logistics system is to be modernised, its information turned into knowledge and its efficiency secured in the pharmaceuticals sector at production, distribution and consumption levels, there needs to be a standardised information management system that successfully engages manufacturers, sellers and buyers. Moreover, efficient operation of such system will only be ensured when distribution information is managed through standardisation of pharmaceutical codes, by promoting drug use safety through pharmaceutical record management and by removing uncertainties in government policy implementations through the establishment of knowledge.

A sound information management system will bring many benefits to the Korean pharmaceutical industry. Not only will it help the industry resolve high cost problem coming from its complex distribution channels, but it will also counter illegal and counterfeit drugs and ensure swift recall of hazardous drugs that affect safety, efficacy and quality. Moreover, the system will promote public health by responding effectively to essential drug shortages, which can escalate into a serious national threat if left unaddressed.





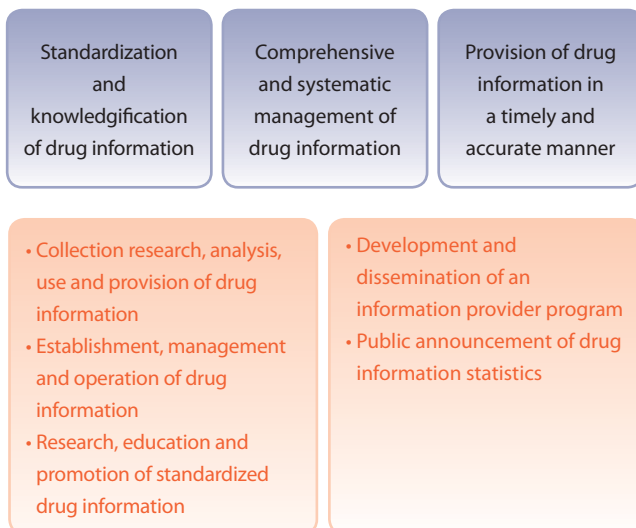
The role of the KPIS

To promote the pharmaceutical industry, the Korean government has taken continuous measures to upgrade the drug distribution system and strengthen industry competitiveness. On October 8, 2007, the government established the Korea Pharmaceutical Information Service (KPIS) as a specialised institution tasked to standardisation of pharmaceutical information and development of knowledge-based information, under the Health Insurance Review & Assessment Service (HIRA) - a public entity established to review and assess medical care expenses under the National Health Insurance Act.

The core function of the KPIS is to collect, study, process, utilise and provide pharmaceutical distribution information with regards to manufacturing, import, supply and consumption activities. Other works of the KPIS include management of Korea Drug codes (including bar codes), informatisation support activities such as development and promotion of programs for collecting distribution information, and research, education for standardisation as well as distribution innovation.

Drug Distribution Information Hub

Promoting National Statistical Infrastructure and Pharmaceutical Industry



Management of pharmaceutical standard codes and bar codes

Used for drug identification purpose, the pharmaceutical standard code is a GS1 Global Trade Item Number (GTIN) made up of country code, manufacturer's code, item reference and check digit. The standard code is assigned to every pharmaceutical product at item/package unit level.

Pharmaceutical Standard Code Structure

Digit	3	4	5		1
Content	Country Code	Company Code	Item Reference		Check Digit
Example	880	6400-6999	Item (including content info) 0001-9999	Packaging Unit 0: Representative Code 1: Packaging Unit	0-9

Bar codes are assigned to drugs by packaging unit and used as in filing code for medical insurance (Effective as of January 1, 2010)

Small quantity batch transaction and duplicate shipping error bring complexities to domestic distribution and are thus deemed to incur excessive logistics cost and weaken competitiveness of the pharmaceutical industry. Against this backdrop, the Korean government introduced and effectuated a bar code label regulation on imported and local-manufactured pharmaceuticals from July 1st, 2000. Imposed to the industry as a mandatory requirement, the label system is designed to bring down logistics cost, ensure transparency in business transaction and facilitate advances in the drug distribution system.

Moreover, in order to expand the scope of application, facilitate bar code usage and seek further improvements, the Ministry of Health and Welfare revised its announcement on the "Guidelines for Use and Managing of the Pharmaceutical Bar code." As a result, the GTIN in the standard KDC (Korea Drug Code) was changed to symbol formats such as EAN-13, GS1-128 and GS1 DataMatrix. Standardisation of drug codes improved information credibility, while informatisation in logistics control reduced cost, enhanced safety in distribution and use and contributed to standardisation of the national drug information database.

Moreover, expiration date and lot number information is mandated in bar codes for traceability of specified drugs from 2012 and prescription drugs from 2013, respectively.

A bar code is required for every medicine distributed in Korea. According the relevant laws and decrees, drugs with missing, partial, unreadable or erroneous bar code information are subject to administrative disposition, ultimately leading to a market pull-out order. The KPIS carries out a field study on the use of pharmaceutical bar codes twice a year to identify new errors and provide education, promotion and counseling accordingly.

Use of bar codes is proven to be beneficial to all participants involved. Pharmaceutical companies can manage distribution information at the source (production, supply and consumption), control dispensing based on a FIFO method and operate a Point-of-Production (POP) system. Wholesalers can manage inventory movement and control stocks more easily. Hospitals, clinics and pharmacies can avoid medication error, as the bar codes provide adequate verification against drugs in stock and appropriate medication control against patients. Lastly, the government can manage drug distribution records by using this system.

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KPIS and GS1 Korea

In February 2009, the KPIS entered into a “Memorandum of Understanding on Promoting Exchange and Cooperation of Pharmaceutical Information” with the GS1 Korea. The MoU allows the KPIS to exchange its drug information with bar code verification information of GS1 Korea. Through information exchange between the two organisations, manufacturers/importers are able to utilise a free and simplified system of pharmaceutical bar code verification. Also, the system reduces bar code error rate by encouraging the manufacturers/importers to attach correct bar code label to their products.

Pharmaceuticals and RFID

The KPIS also oversees pharmaceuticals applying RFID, which is now in a pilot stage available to a few companies. As an effort to advance and improve transparency in drug distribution, the Korean government plans to push RFID usage to 50% levels in the pharmaceutical industry by 2015.

Based on a pharmaceutical RFID pilot project from 2006 to 2007, the KPIS is also drafting a revised announcement and operating guidelines to promote usage of pharmaceuticals with RFID tags. The KPIS will also launch a consumer pilot project to test provision of drug information and develop an internal system to check distribution flow of drugs with RFID tags.

If RFID becomes more popular in the logistics process and dispensing status gets reported to the KPIS on a real-time basis, then they will surely contribute to improving pharmaceutical use traceability, which in turn will counter use of counterfeit drugs and recall hazardous drugs, thereby improving quality of national health.

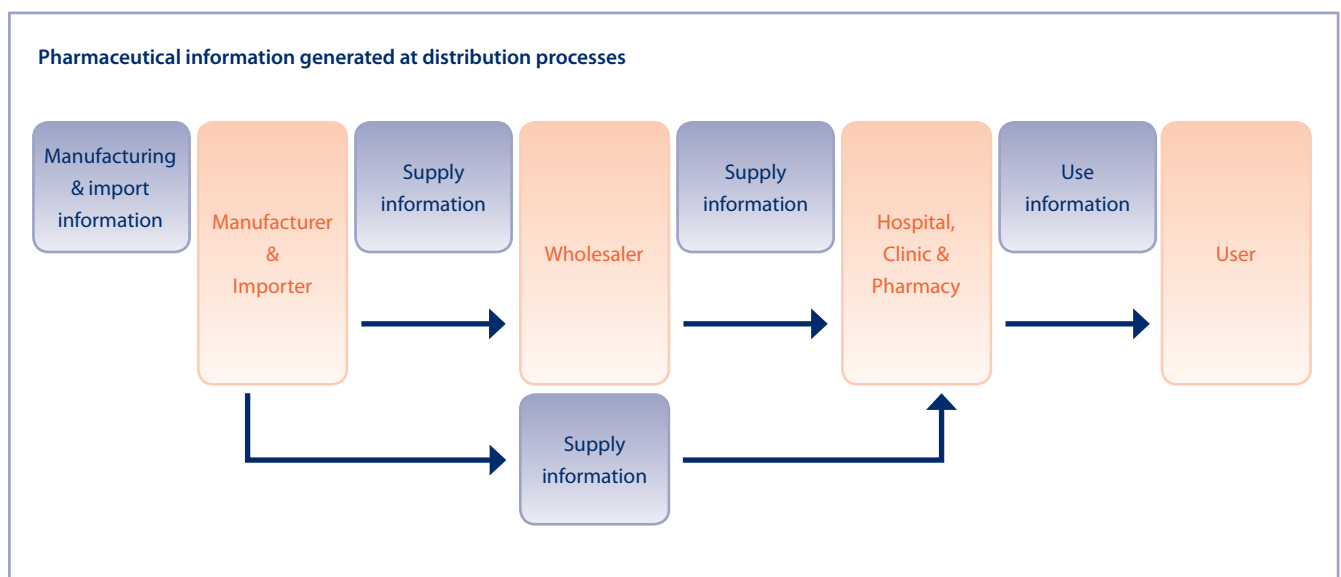
Information collection and management

The legal grounds for collection of pharmaceutical distribution information comes from the Pharmaceutical Affairs Act and the National Health Insurance Act, which require collection and management of information related to production, import, supply and consumption of drugs in Korea. Supplier information is created at manufacturer, importer and wholesaler levels, while user information is generated at hospital, clinic and pharmacy levels.

Performance records show the current status of drug manufacturing/import. As for drug supplier/user category, the purpose is to show market status, promote distribution record keeping, upgrade logistics capability and ensure transparency. The objective is to advance drug distribution and support reimbursement approval activities. Information in the user information category can be used to support review and payment of insurance benefit claims.

Manufacturing / import performance is recorded by requiring manufacturers/importers to submit quarterly performance report to the relevant associations, which then relays the report to the KPIS. As for drug supply details, suppliers are required to submit their monthly transaction records with medical institutions, pharmacies and pharmaceutical wholesalers to the KPIS.

Once collected, information is cross-analysed to identify the accurate distribution flow at the logistics level. Also, field investigations are conducted to push for accurate reporting from suppliers. Enhanced transparency in drug distribution promotes fair trade of pharmaceutical products. Moreover, as pharmaceutical distribution information grows in volume, it is able to provide official data on the Korean market situation. Those outside the pharmaceutical industry can now utilise statistical information on drugs provided on a regular basis.



Analysis and utilisation

When the KPIS can collect drug distribution information in a timely and accurate manner, accumulate multi-year information base from which various relevant statistics are produced and manage pharmaceutical bar codes in an error-free manner, those outside the pharmaceutical industry can also benefit from access to such information.

- Advances in drug statistics management will be realised through establishment of a national statistics infrastructure that contains information on pharmaceutical industry, drug distribution industry and current status of drug use by the general public.
- The KPIS can contribute to transparency in pharmaceutical distribution and soundness in insurance finances.
- Drug history can be traced back, which means illegal, counterfeit and hazardous drugs can be managed thoroughly and recalled whenever necessary. The KPIS can contribute to enhanced public safety with regards to the people's drug use.
- The KPIC can fulfill the needs of pharmaceutical companies on market information and contribute to their business efficiency in terms of new product development, manufacturing and inventory control.
- Facilitated use in pharmaceutical standard code (bar code) can improve distribution efficiency such as order placements, delivery and inventory control and link the acquired information for further knowledge of information.

Conclusion

Recently, developed countries are found to show more interest in the management of public health safety, which refers to a series of systematic efforts to reduce or eliminate risk factors that are/could be found in medical institutions. Since most patients get prescription treatment in outpatient clinics, accuracy in drug dispensing becomes the highest priority issue in patient safety management.

In this regard, the use of a pharmaceutical bar code to eliminate medication errors is an important aspect of public safety management. In line with the drug standardisation policy since January 2008, the standard code is assigned to every pharmaceutical product in Korea and bar code labeling preparation is required at manufacturer/importer level.

In future, it is expected that traceability will enhance patient safety and enable efficient medical support through the established on-line network. Information collection, advanced studies on future market, and product recalls will be carried out accordingly. In future, Korea will follow other countries to introduce bar code and RFID usage in medical devices and other public health products. Patient safety and economic efficiency need to be further improved through systematic approaches including pharmaceutical use traceability.

If Korea is to maximise benefits of information technology in public health sphere, data structure, carrier and exchange need to be based on a global standard.

In future, the KPIS will play the central role in creating value out of and sharing drug information among manufacturers, importers, wholesalers and medical institutions in Korea. Through these efforts, the KPIS will contribute to development of pharmaceutical and distribution industries and promote safe use of drugs by the general public.

ABOUT THE AUTHOR

Jeong, Jeong-ji, Head of the Korea Pharmaceutical Information Service Center

Jeong, Jeong-ji is the head of the Korea Pharmaceutical Information Service Center, an organisation affiliated with Health Insurance Review & Assessment Service. Head Jeong earned a master's degree in Public Health Administration from Sungkyunkwan University in 2000 and a Ph.D. in Business Administration from Konyang University in 2008, respectively. She joined the HIRA (formerly known as the National Federation of Medical Insurance until 1999) in September 1979 and has worked for the national health insurance.

Dr. Jeong developed the model to assess pharmaceutical expenditure's appropriateness in 2000. She pushed ahead with the business to standardise the medical device code for medical product traceability management system and developed a voluntary model to improve optimal integration in 2008. She also developed the total profile system for Healthcare provider in 2009 and built a management system to trace fees for medical services and developed fees for medical services to implement u-Health in 2010, respectively.