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Trends of Market and Approval Management System for in vitro Diagnostic Veterinary Medical Reagents in Korea

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Abstract : In vitro diagnostic veterinary medical reagents (IVDVMRs) were diverted the medical devices from medicine by the revision of the pharmaceutical affairs act enforcement regulations in 2015 in Korea. It classified into class I-IV according to risks of individual and public health. However, good manufacturing practices requirements on IVDVMRs were exempted from the current system. The registration of IVDVMRs by the Animal and Plant Quarantine Agency has gradually increased since 2012, and total of 584 products from 68 companies were registered from 1978 to 2017. Most of these items are clinical immunochemistry (infection disease), clinical immunochemistry (non-infection disease), molecular genetics, endocrinology, blood gas analysis, clinical microbiology, toxin, heavy metal and drug of abuse, other etc. The market size of IVDVMRs reported from the Korea Animal Health Products Association was estimated to be approximately 51.9 billion won in 2017. The domestic consumption and the export sales were approximately 31.2 and 20.7 billion won, respectively. They are increasing 23.9% (CAGR) in domestic consumption and 40.4% (CAGR) in export from 2011 to 2017.

Key words **:** in vitro diagnostic veterinary medical reagents, regulation management system, registration, sales.

Introduction

Recently, diagnostic devices market has been increasing due to an increasing interest in health followed by aging and improvement of the standard of living all over the world. The market has been expanding due to the entry to the healthcare industry of large multinational corporations and the development of IT and BT technology, which enables the rapid and accurate diagnosis of in vitro diagnostic reagents with improved performance. Reflecting this trend, the global diagnostic reagent market revenue grew at an average annual rate of 5.4% from $ 38.762 billion in 2009 to $ 50.379 billion in 2014 (8). In addition, since in vitro diagnostic medical devices can provide information necessary for the prevention and treatment of diseases, related regulations are being reorganized in terms of protecting the public health and operating internationally harmonious and reasonable rules (11).

In recent years, the number of companion animals in several countries such as Korea, United States, Europe, and Japan has been increasing, and the level of quality requirements for companion animals in the medical field has increased, leading to early diagnosis of diseases and proactive prevention. These influences have led to the introduction and use of in vitro diagnostic analyzers and reagents for infectious and non-infectious diseases more frequently. Thus, the application for registration and licensing of in vitro diagnostic reagents for animals has increased (2). However, there are obstacles to industrial development due to limited information for certain areas such as approval management system, product registration and sales status of animal diagnostic reagents worldwide, including Korea. Therefore, this study reviewed trends of market and approval management system for in vitro diagnostic veterinary medical reagents (IVDVMRs) in Korea.

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Definition and Scope of In Vitro Diagnostic Medical Devices (IVDMDs)

The Global Harmonization Task Force (GHTF) defines that IVDMDs include medical devices, reagents, calibrators, quality control materials, sample containers, software, related devices or equipment that enable to conduct in vitro tests of tissues, blood, and urine samples from human and provide information to diagnose or monitor of patients, or determine suitability (9).

In Korea, the Ministry of Food and Drug Safety (MFDS) defines the in vitro diagnostic reagent as a reagent for the reaction and analysis using the medical device in consideration of the international trend. It is divided into the main reaction reagent and the supportive reagent. The main reaction reagent is a reagent such as antigen, antibody, primer or the like, which is used for the purpose of determining the presence or absence of a disease in a human body by detecting or measuring a substance in the sample derived from the human. The supportive reagent is defined as a component that is used as an adjunct in the use of an in vitro diagnostic reagent, but not used as a medical device by itself, but with the main reaction reagent (18).

Changes of Regulatory Management System on In Vitro Diagnostic Veterinary Medical Reagents (IVDVMRs)

In developed countries such as the United States, Europe, and Japan, as shown in Table 1, in vitro diagnostic reagents, which were autonomously managed in the past, have been graded according to their importance and risk to health from the early 1990s, and based on their grades, licensing and registration were made differentially. In the United States, in vitro diagnostic reagents are classified into Class I, II, and III according to their intended use and risk. Most in vitro diagnostic reagents are supervised by the office of in vitro diagnostic of the Center for Drug and Radiological Health (CDRH) (27). In Europe, in vitro diagnostic reagents are classified as other, List A and B according to the risk, and the technical documents are examined by designated institutions (7). In Japan, unlike other countries, equipment is classified as a medical device, and in vitro diagnostic reagents are classified as biological drugs under the control of the Pharmaceutical Affairs Act, and classified into Class I, II, and III according to the risk (10).

In Korea, before 2000, the medical device was recognized as an accessory of medicine and it was managed by the Pharmaceutical Affairs Act. However, there was a limit to the management as the role and size of medical devices gradually increased. In May 2003, the Medical Devices Act was enacted (6) and medical supplies managed by the Pharmaceutical Affairs Act were converted to those managed by the Medical Devices Act. However, in vitro diagnostic reagents used for diagnosis of infectious diseases were managed as biological agents under the Pharmaceutical Affairs Act. In 2007, they were changed to in vitro diagnostic medicines. However, the reagents for biochemical automatic analyzers excluded from the license under the Pharmaceutical Affairs Act were treated as parts of analytical instruments and still managed as industrial products (22).

In 2009, when the novel influenza pandemic occurred in Korea, the issue of the neglect of the management of the reagents directly reacting with the clinical specimens was raised, and the system for approval of the in vitro diagnostic reagents was started to be organized. Thus, in 2011, the Enforcement Rules of the Medical Devices Act was amended to establish standards for classification of medical devices and items and regulations for approval and review. In May 2013, regulations on the classification of medical devices and items were revised, and the classification was changed from the analyzer type based to the clinical field based. Since January 1, 2014, all of the in vitro diagnostic reagents that were managed as industrial products were included as medical devices (11). In addition, products that can be visually judge such as the pregnancy diagnostic kit were managed as medicines according to the Pharmaceutical Affairs Act, and it raised a problem about the dualized management system. Since December 31, 2014, for international harmonization and convenience of industry and consumers, the products in the dualized management system were unified to medical devices. And the name of the reagent for in vitro diagnostic analyzer has been changed to an in vitro diagnostic medical device (Table 2) (12).

Current Status of Approval Management Systems for IVDVMRs in Korea

In Korea, veterinary medical devices including in vitro diagnostic reagents are managed based on the special provision of the Pharmaceutical Affairs Act and the Medical Devices Act, so the regulatory management system of veterinary medical devices are basically similar to those for the medical devices of humans. In October 1957, the Pharmaceutical Affairs Act was amended to administer medical supplies or sanitary materials intended for livestock and poultry, under the supervision of the Minister of Agriculture and Forestry. In July 1965, the Rules for the Handling of Veterinary Drugs were enacted by the Ministry of Agriculture and Forestry, and veterinary medical supplies were classified as stethoscopes in Annex 1. In July 1992, the Pharmaceutical Affairs Act was revised and newly established the special provision for veterinary drugs. In December 1999, the amendment of the "Regulation for Delegation and Consignment of Administration Authority" transferred the management of veterinary drugs from the Ministry of Agriculture and Forestry to the National Veterinary Research and Quarantine Service. In May 2003, medical supplies controlled by the Pharmaceutical Affairs Act were converted to medical devices. In May 2004, it was converted from veterinary medical supplies to veterinary medical devices by the Enforcement Ordinance of the Medical Devices Act. In September 2011, the Rules for the Handling of Veterinary Drugs were amended as in Table 3 to establish the standards and procedures for classification and designation of veterinary medical devices as in the humans, as a result, they were classified

Table 1. Comparison of the national regulation management system of IVDVMRs

Country	GHTF*	USA	Japan**	EU	Korea
Classification system	IVDD*	Medical devices	IVDD	IVDD	IVDD
Number of Class	4 (I,II,III,IV)	3 (I,II,III)	4 (I,II,III,IV)	4 (I,IIa,IIIb,III)	4 (I,II,III,IV)
Principle of classification	Level of individual and public health	Intended use, indication and level of risk	Level of risk	Level of risk	Level of individual risk and public health
Applied rules	7 Rules and examples	Lists	Rules and lists	Rules and lists	Rules and lists

*GHTF: Global Harmonization Task Force, IVDD: In vitro diagnostic devices.
**Japan has a separate system for classifying reagent and medical devices for IVDD, and all IVD medical devices are classified into Class.

Table 2. History of regulatory management system of IVDVMRs in Korea

Date	Event of regulatory management system of in vitro diagnostic reagents (reference)
1953.12.18	Enactment of the pharmaceutical affairs act for management of medical drug and supplies (Ministry of Health and Society) (22).
1957.10.05	Revision of pharmaceutical affairs act (Medical supplies or sanitary materials for livestock and poultry) (23).
1965.07.15	Revision of pharmaceutical affair act, Enactment of handling rules of animal medicines, etc (Management of medical appliance for animal) (16).
1992.07.01	Revision of pharmaceutical affairs act (Establishing provisions of special exceptions for animal medicines, etc) (24).
1995-2006	Notification of veterinary medical device from Korea Animal Heath Product Association (2).
1999.12.31	Transfer of management of veterinary drugs, etc. from ministry of agriculture and forestry (currently, MAFEA) to national veterinary research and quarantine service (currently, APQA) (25).
2003.05.29	Enactment of medical devices act and management of special exceptions for medical devices for animals by article 39 (15).
2004.05.25	Revision of enforcement decree of the medical devices act (The change of from veterinary supplies to veterinary medical devices) (13).
2007.05.04	Revision of pharmaceutical enforcement rule of pharmaceutical affair act. (The change from biological material to in vitro diagnostic drug) (21).
2007.11.30	Establishment of pharmaceutical management division for veterinary drugs, and devices in NVRQS (currently, APQA)
2011.07.28	Revision of regulations on the scope and designation of veterinary medical devices (The establishment of items and grades of the in vitro diagnostic reagents used for the detection) (19).
2011.09.20	Revision of enforcement rule of veterinary drug, etc (Establishment of regulations and process on the scope and designation of veterinary medical devices) (5).
2011.11.25	Revision of enforcement rule of veterinary medical devices (Establishment of investigation data and GMP interim measures of the in vitro diagnostic reagents used for the detection) (14).
2011.12.30	Revision of regulation on approval, notification, audit and etc of medical devices (Establishment of investigation data of definition and technology document etc for the in vitro diagnostic reagents used for the detection) (17).
2012.12.28	Enactment of regulation on permit for veterinary medical devices and regulation of technical of documents audit for veterinary medical devices (3).
2013.05.08	Regulation on grade of medical devices item and by item (All revision of rating by item) (20).
2014.05.09	Revision of enforcement regulation of the medical devices act (The unification of management systems for in vitro diagnostic products) (12).
2014.10.31	Revision of regulation on approval, notification, audit, etc of medical devices (The plan preparation of regulation maintenance and evaluation efficiency for management unification of in vitro diagnostic products) (18).
2015.08.21	Revision of regulations on the approval of veterinary medical devices (The unification of management systems for in vitro diagnostic reagent) (4).
2016.01.01	Revision of regulations on the approval of veterinary medical devices (The renewal of licensing in vitro diagnostic reagent used to catching an animal infectious disease and beginning of licensing for molecular diagnostics including PCR) (4).

into four grades and the grading system was enforced from January 1, 2014.

In vitro diagnostic reagents used for the diagnosis of infectious diseases were classified as biological agents that belong to medicines in the past, but reagents and media for molecular genetic testing were not included in the scope of in vitro diagnostic reagents. In addition, a variety of in vitro diagnostic reagents used in the diagnosis of non-infectious diseases were excluded from in vitro diagnostic medicines, thus placing them in the blind spot of legal management. Therefore, in August 2015, we revised the regulations for the approval of veterinary medical devices, similar to those of medical devices for humans, to unify all the in vitro diagnostic veterinary reagents into medical devices. From January 2016, we converted the in vitro diagnostic reagents used in diagnosis of infectious diseases in animals into medical devices. And reagents for molecular diagnostic genetic testing, which have already been sold, have been processed for license, and currently 584 products are being reviewed for license.

Licensing System for IVDVMRs and Registration Status in Korea

Animal and Plant Quarantine Agency (APQA) revised the regulations related to in vitro diagnostic reagents in August 2015 in order to harmonize with the medical devices for humans, establishing standards for product classification and approval. The classification criteria are classified into I to IV

Table 3. Change of Korean regulatory management system for IVDVMRs in 2015

Classification		Regulation on the management system of in vitro diagnostic reagent		Remark (Human)
		Current	Revision	
Item	Equipment	Medicine device	Medicine device	The same as human
	Reagents	Biological medicine		
Grade	Equipment	I-IV	I-IV	The same as human
	Reagents	No Application		
Scope of reagent for IVD		The diagnostic reagents such as media and IVD reagents for molecular genetics have neither classification nor grade system IVD reagents for hematology have set-up as component of equipment	49 category classification of reagents for IVD	The same as human
Good manufacturing practice (GMP)		No application	No application	Application (II~IV grade)

Table 4. Comparison of the registered products from company IVDVMRs in Korea by 2017

		No. of registered by year																	Total
		~01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	
Company	Import	0	0	0	0	1	1	0	5	4	5	1	1	1	4	7	5	4	39
	Manufacture	0	0	0	1	0	0	0	0	0	1	0	2	0	2	2	16	5	29
	Total	0	0	0	1	1	1	0	5	4	6	1	3	1	6	9	21	9	68
Products	Import	8	1	1	0	4	1	0	0	1	1	0	4	0	1	13	164	16	215
	Manufacture	14	5	5	8	9	6	8	15	23	5	5	26	12	21	14	76	117	369
	Total	22	6	6	8	13	7	8	15	24	6	5	30	12	22	27	240	133	584

grades according to the purpose of use, individual risk, and public health risk. In other words, if the individual risk and the public health risk are lowest, the grade is I; if the individual risk is moderate and the public health risk is low, the grade is II; if the individual risk is high and the public health risk is moderate, the grade is III; if both the individual and public health risks are high, the grade is IV. The grade I is classified as a product required to report only, but the grades II-IV must be licensed (28). Good manufacture practices (GMP) have not been applied in veterinary medical devices, although they are controlled in a manner similar to the medical devices for humans in terms of quality management, post management, and labeling for advertising.

According to the licensing system, there were 68 companies licensed to the APQA from 1978 to 2017, with 39 imports and 29 manufactures, accounting for a ratio of imports to manufacture of 5.7: 4.3. Of these companies, 39 (57.4%) were found to be licensed in 2015-2017 when the management of in vitro diagnostic reagents was unified (Table 4). A total of 584 products were reported or approved by these diagnostic reagents. Of these, 215 were imported and 369 were manufactured in Korea. Table 4 shows that the registration rate of in vitro diagnostic reagents increased rapidly in 2016 when reagents were separated from in vitro diagnostic equipment.

In comparison of all 584 products, 448 reagents were for clinical immunochemistry, 50 for molecular genetic testing, 46 for hematology, 13 for strips, 11 for clinical microbiology, 7 for transfusion, 6 for urine or fecal examination, 1 for pathology and 2 for other tests. The rate of registration of chemical reagents for immunochemical test was 22.4% for non-legally designated infectious pathogens by OIE, 17.5% for immunochemical test, 16.8% for the immunological test of zoonosis, 12.2% for legally designated infectious pathogens by OIE, 3.8% for endocrine substance test, 1.7% for blood gas analysis, 0.9% for allergy test, 0.7% for cardiac marker, 0.34% for tumor marker, 0.17% for therapeutic drug monitoring, 0.17% for toxin and 0.17% for autoimmune disease test (Table 5).

Trends and Prospects of Market for IVDVMRs

It shows the sales results of domestic in vitro diagnostic reagent makers and importers reported to Korea Animal Health Products Association (KAHPA) for the last 7 years from 2011 to 2017. Sales for the three years from 2011 to 2013 were estimated at about 12 billion won, with domestic sales of 8 billion won and exports of 4 billion won. Most of the sales are ELISA and Rapid kit, which are used to diagnose animal infectious diseases. The top 9 items with high sales were clinical immunochemistry (infection disease), clinical immunochemistry (non-infection disease), molecular genetics (infection disease), endocrinology, hematology, blood gas analysis, clinical microbiology, Toxin, heavy metal and drug of abuse, other etc (Fig 1).

Table 5. List of products for IVDVMRs licensed by 2017

Category	Products	No. of registered
Hematology	Blood test (including IVD supportive reagents for blood test)	32
	Hemostasis and thrombosis	14
Transfusion	Blood typing	7
Urine or feces	Urine chemistry	6
Clinical immunochemistry	Clinical Immunochemistry	102
	Cardiac marker Myoglobin	4
	Therapeutic drug monitoring	1
	Toxin	1
	Tumor marker	2
	endocrine substance test	22
	Autoimmune disease	1
	Allergy test	5
	Blood gas analysis	10
	Immunological method for zoonosis disease	98
	Immunological method for legally designated infectious pathogens by OIE	71
	Immunological method for non-legally designate infectious pathogens by OIE	131
Clinical microbiology	Staining or culturing clinical microbiology	9
	IVD reagents and media for antibiotic susceptibility	2
Molecular genetics	Molecular genetics for zoonosis disease	14
	Molecular genetics for legally designated infectious pathogens by OIE.	19
	Molecular genetics for non-legally designated infectious pathogens by OIE.	12
	Extracting nucleic acids	5
Strip	Strip for self testing	5
	Strip for high throughput	8
Pathology	Tissue stain and histopathology	1
Other tests	Calibrators for controls or standards	2

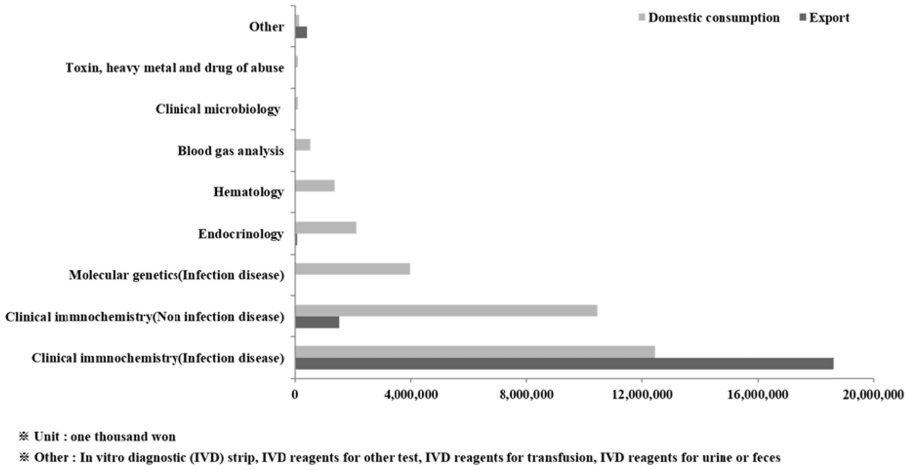

Fig 1. The distribution on sales of IVDVMRs in 2017.

Total sales in 2015 and 2016 were 24.1 billion and 38.1 billion won, respectively, but it increased sharply in 2017 with sales of 51.9 billion won (31.2 billion won for domestic sale and 20.7 billion won for export). Therefore, they are increasing 28.9% (23.9% in domestic consumption and 40.4% in export) (Compound Annual Growth Rate; CAGR)

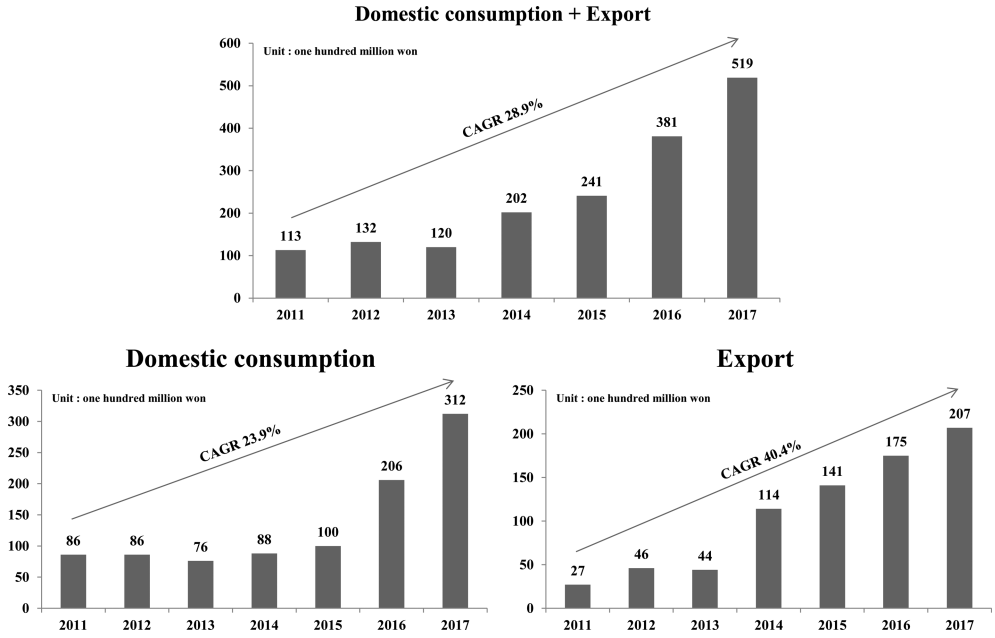

Fig 2. The annual sales amounts of domestic consumption, export and compound annual growth rate (CAGR) IVDVMRs from 2011 to 2017.

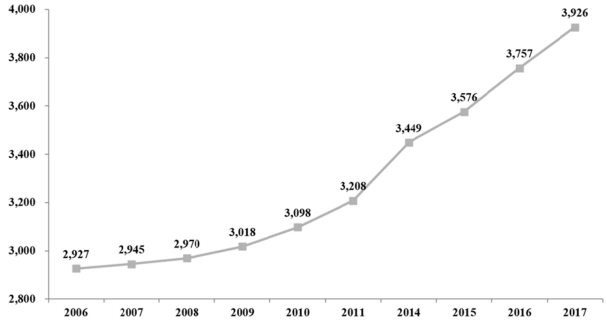

Fig 3. The changes on the number of animal hospital from 2006 to 2017.

from 2011 to 2017 (Fig 2). Compared to domestic consumption and export sales, exports were 2.95 time higher than domestic consumption sales. This is due to the fact that non-infectious in vitro diagnostic reagents such as immunochemistry, blood gas analysis, endocrine substance, autoimmune disease and allergy test are included in the range of veterinary medical devices and a steady increase in manufacturers' exports. These results are supported by the sales data of 2016 and 2017 when was unified in the licensing of in vitro diagnostic reagents.

Currently, in Korea, in vitro diagnostic reagents for veterinary are widely used in veterinary clinics, ranging from industrial animals such as cattle, pigs, and chickens to companion animals such as dogs and cats. They play a very important role in veterinary clinic practices. For example, the number of animal hospitals in Korea in 2017 was 3,926 and increased 34.1% (2,927) than 2006 (Fig 3). Due to these factors, product registration and sales of in vitro diagnostic reagents for animals have been rapidly increasing since 2016. Along with the increased number of companion animals in Korea, the improvement of high quality medical services, securing the safety of food in industrial animals, and the improvement of productivity have been recently highlighted as major issues (1). Thus, in vitro diagnostic veterinary medical devices industry is expected to grow further in the future.

Conclusion

In order to harmonize with other countries in the world, the MFDS has been restructuring licensing procedures and requirements such as scope, classification and grading of products as medical devices for in vitro diagnostic reagents. For in vitro diagnostic reagents for animals, the regulations on licensing were revised in 2015 in order to harmonize with medical devices for humans, thus laying the foundation for a rapid approval management system. As a result, various kinds of products related to blood gas analysis, endocrine substance, autoimmune disease and allergy test have been included in the range of veterinary medical devices and sales performance has increased sharply. However, compared with the medical devices for humans, in vitro diagnostic reagents for animal are required to improve regulations related to the licensing system, providing various information and preparation of reference standard. In addition, the GMP system has not yet been applied, so it should be reviewed and prepared. Therefore, it is necessary that the foundation for supplying safe and effective in vitro diagnostic products should be provided within a short time to improve the quality of the products through such regulations improvement.

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