ORIGINAL ARTICLE

Study of commercial product range and rules of use of medical thermometers

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Abstract

Aim: The aim of this study is to analyze the assortment, purpose, principles of work, and commodity characteristics of medical thermometers, which are present in the modern pharmaceutical market of Ukraine. **Materials and Methods:** Logical and analytical methods were used for the analysis of the data of specialized literature and the regulatory legal framework, as well as the data of the state registration, which are presented in the state register of medical equipment and medical products in the group: Medical thermometers. **Results and Discussion:** The commercial product range of medical thermometers, their varieties and structural features, and principles of work is analyzed. The data from our carried out research work indicate the relevance of further study for this assortment segment of medical products to systematize medical thermometers and analyze in detail the consumer characteristics of them. **Conclusions:** Based on the analysis of the Ukrainian market, it was established that the dominant positions in the range of medical thermometers were occupied by foreign manufacturers from China, Japan, USA, Great Britain, and Germany. Ukraine needed to improve its own research in the field of development of new types of this product, as well as to take over the experience of foreign manufacturers regarding the variety of additional functions for thermometers, their range, and methods of their manufacture.

Key words: Classification, commercial product range, commodity expert analysis, medical thermometer, purpose, structural features, thermometry

TOPICALITY

At present, the Department of Commodity Science introduces the teaching of new topics in the discipline "Medical and Pharmaceutical Commodity Science," in particular, "commodity analysis of medical devices and apparatus." The main task of the department is to provide students with theoretical knowledge and practical skills when working with a range of medical devices, which is definitely useful for the practical activities of future pharmacists. The study of the commercial product range of medical thermometers is one of the segments of this topic.

Thermometer is one of the most used diagnostic medical devices. The systematization of knowledge of the modern range of medical thermometers will help the pharmacist to professionally carry out all stages of pharmacology at the implementation of thermometers and explain to the consumer about all the advantages or disadvantages of this type of product, to orient him when selecting and purchasing these devices.[1,2]

During the treatment of colds and viral diseases, body temperature should be monitored regularly. For this purpose, medical thermometers of various modifications are used, for measuring the temperature inside the armpit, rectally or in other ways, depending on the specifics of the disease or the benefits for the consumers. When using mercury thermometers, there is a risk of poisoning with toxic mercury vapors in the event of damage to this thermometer.

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Not all consumers are aware of the degree of responsibility in such cases, and not everyone knows how to behave safely when eliminating the effects of damage to thermometers and how to properly dispose of them.[3,4]

Now, the pharmaceutical market offers consumers a fairly wide range of medical thermometers of domestic and foreign production. This study was intended to analyze the domestic market of medical thermometers, to evaluate their consumer characteristics, the principles of work, and the specifics of the purpose of this type of merchandise.[5]

The aim of this work is to analyze the assortment, purpose, principles of work, and commodity characteristics of medical thermometers, which are present in the modern pharmaceutical market of Ukraine.

MATERIALS AND METHODS

Logical and analytical methods were used for the analysis of the data of specialized literature and the regulatory legal framework, as well as the data of the state registration, which are presented in the state register of medical equipment and medical products in the group: Medical thermometers.[6]

RESULTS AND DISCUSSION

An important diagnostic value is the change in body temperature. Fast and accurate diagnosis of diseases with the use of highly effective methods of non-invasive diagnosis is a current necessity for modern medicine. Thermometry of the human body is historically the first method of quantitative assessment of one of the parameters of the vital activity of the organism by means of a special device. The inventor of the thermometer is considered to be Galileo.

A modern thermometer (Greek θέρμη – heat) is a medical device for measuring body temperature, air, food, and water. The principle of its work is based on the properties of the fluid to expand under the action of heat. Thermometry is the process of measuring body temperature using a thermometer (Greek *thermo* – heat, *metreo* – to measure).[7]

All known temperature-measuring devices can be divided into the groups: Contact, non-contact, and electro-contact.

The classification of medical thermometers is as follows: Liquid (alcohol and mercury); electronic (digital, baby's thermometer-dummy, and thermometer-bracelet); infrared (ear, frontal, and temporal); thermal tests; or thermosensitive strips.

We explored the range of medical thermometers offered to consumers in the modern pharmaceutical market.[6] The results are presented in Table 1.

Liquid thermometers are the most widespread type of thermometers, the principle of which is based on the thermal expansion of chemicals (mercury, kerosene, ethyl alcohol, pentane, toluene, etc.). Compared to other thermometers, mercury has significant advantages due to the properties of the chemical used: High accuracy of measurements: Up to 0.05-0.1°C, durability and long-operating life (with proper handling and storage – more than 15 years), easy disinfection, and low cost.[8]

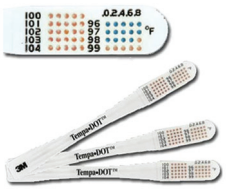
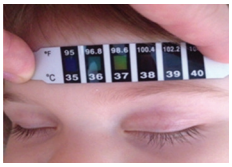
The disadvantages of this type of thermometers are fragile body material; toxicity of the filler (mercury), which, if the

Table 1: Analysis of commercial product range of medical thermometers in the modern pharmaceutical market

Types of thermometers and their brief description	Structure of thermometers (original appearance)
Mercury thermometers are one of the most accurate instruments for measuring temperature. Their principle of work is based on the ability of mercury to expand when heated. Mercury thermometer has a shell of thin glass, part of which is a small reservoir of mercury, connected with a thin glass tube - a capillary fixed on the scale inside the shell. The scale of thermometer is designed to determine the body temperature to accuracy of 0.1°C, for which it is applied appropriate divisions. The term of service is unlimited. Limit of permissible error±0.1°C. One scale division is equal to 0.1°C. Range of temperature measuring: From 35 to 42°C.[1] When measuring the temperature, the mercury contained in the reservoir is heated and displaced inside the capillary to a level of a certain division mark on the scale. Thermometer captures the maximum temperature, that is, the highest division mark to which the mercury has risen. The readouts of the thermometer do not change after finishing the temperature measurement, because mercury can go down into the reservoir only when shaking the device: It is prevented by a narrow in the lower part of the capillary	

(*Contd*...)

Table 1: (Continued)

Types of thermometers and their brief description	Structure of thermometers (original appearance)
Electronic digital thermometers are plastic devices in the form of a pencil or a finger (Latin *digitalis*). There is a sensor on the narrow end of the plastic container, and on the expanded one, there is a display, the battery compartment, and the thermometer on/off button. An electronic thermometer can measure the temperature inside the armpit, orally, rectally. After pressing the power button, a beep will sound, the symbols appear on the display – the instrument is being calibrated. After the symbol Lo appears, the thermometer is ready for operation. After 1 min or a few seconds (depending on the model of the instrument), a measurement result appears that can be read out, and the thermometer can be turned off. The device has an electronic memory that is convenient for monitoring the temperature dynamics	 
Baby's thermometer dummy is a device structure that recreates the shape of a baby's dummy made of latex or silicon. To measure the temperature, the thermometer is placed in the mouth of a child as a regular baby's dummy. The display is mounted on the outer side to show the temperature readings. The device is equipped with an on/off button. Many of the varieties of this modification of the thermometers have a backlight that provides a comfortable temperature measurement at the night. The indicator can show the temperature at the change of color signal (at normal temperature, it is green, at high, it is red), as well as give numerical temperature readings	
Thermometer bracelet is one of the progressive types of thermometers. It allows for constant monitoring of the body temperature of the child, sending information to the parents' smartphone. When the temperature rises, the bracelet emits a certain sound signal. The disadvantages include the impossibility of implementing specific measurements: The bracelet allows to know just the overall body temperature, plus the cost of the device is high	
Disposable thermometers are thin plates with color-dotted markings and temperature values at the end. The temperature is determined by the color of the dots 3M Company has developed Tempa DOT™ disposable sterile thermometers for measuring body temperature orally, rectally. and inside the armpit. Tempa DOT™ is individually packaged and is not reused, eliminating the risk of transmission of harmful microorganisms. The accuracy of temperature measurements and the ease of interpretation of the result are provided	
Liquid-crystal thermometers, thermosensitive strips, instant thermometer "Thermotest" measure the temperature on the forehead skin. They have the form of plastic plates with several temperature values, changing color at elevated temperature To measure the temperature, the thermo test should be pressed for 2-3 min against the skin on the forehead. It shows the temperature approximately: Only above or below the critical mark (37, 39, 40°C). At a temperature of 36-37°C, the letter "N" (Norm) appears in green, and at a temperature above 37°C, the letter "F" appears in red (fever). The exact increase of temperature is then determined by a medical thermometer. This device is quite practical on the trip, but its service life is only 1 year, and the readings are significantly influenced by the ambient temperature	

(*Contd*...)

Table 1: (Continued)

Types of thermometers and their brief description	Structure of thermometers (original appearance)
Infrared thermometers allow to measure temperature without the need for direct contact with the skin. The principle of operation is based on determining the power of the thermal radiation of the measurement object in the ranges of infrared radiation and visible light. The measurement speed is from 5 to 30 s	
A portable contactless pyrometer Kelvin. A pyrometer is a device for contactless measurement of temperature, which is used in industry and in everyday life (measurement of body temperature, food, water, etc.). According to the Interstate Standard GOST 28243-96 "Pyrometers – General Technical Requirements," a pyrometer is a means (a set of means) for measuring the temperature by thermal electromagnetic radiation, designed to issue a measurement information signal in a form that is convenient for direct perception by an observer. The principle of operation is based on the measurement of the thermal radiation of the object in the ranges of infrared radiation and visible light. The possibility of instantaneous remote temperature measurement of the body areas allows to obtain information about the difference in temperature of individual points with an accuracy of 0.1°C and to detect body areas with anomalous temperature. The device allows non-contact temperature measurement of objects at a distance from 25 cm to 5-10 m, a function of storing the last measurement result, a memory for 1000 measurements, the ability to connect to a PC, auto shut-off. The temperature range measured by the pyrometer is from−20°C to +200°C (up to +600 and up to +1500°C in various modifications). The accuracy is ±2°C or ±2% of the measured value	
Ear thermometers (infrared) are plastic devices of various shapes, whose operation is based on measuring the energy of infrared radiation. The cone-shaped end of the thermometer is placed in the ear canal, and the temperature reading is shown on the display. Some models indicate the prescribed temperature when measuring orally and rectally	
Infrared thermometer for measuring temperature "3 in 1." Waterproof infrared thermometer provides accurate and fast measurement of body temperature in the ear or on the forehead, determination of surfaces or water temperatures. Particularly, convenient for measuring the body temperature of children	

thermometer gets broken, can damage the patient's health and poison the premises for a long time; relatively low measurement speed (5-10 min); difficulty in taking readouts without sufficient illumination or at visual impairment; and complexity of measuring the temperature in young children who do not want to sit quietly for the required time. The lack of risk determines the safety of this type of thermometers for patients of all ages.

The advantages of electronic thermometers are as follows: They do not contain mercury, the plastic case is shock resistant (some models are waterproof), the devices are equipped with an acoustic signal, a memory, an automatic switch off, a timer, a display backlight, and in some models, there is an enlarged display with large numbers.

The advantages of infrared thermometers are as follows: High degree of hygiene, since the device that did not touch the skin of the patient practically does not need to be washed and disinfected; measuring body temperature without contact with the skin, even in newborn infants, due to a sensitive element that responds to infrared radiation of the body and reads information, reflecting the results of measurements on the liquid-crystal display; high speed of getting measurement results (up to 30 s); the kit includes removable tips that are easy to rinse and disinfect, and also

there are additional accessories on sale; maximum safety: Absence of toxic elements (mercury), as well as fragile traumatic glass; the contactless technique of measurement allows also to determine the temperature of water, air, and food mixture for infants; and high functionality (equivalent to electronic thermometers). The disadvantages of infrared and electronic thermometers are a fairly high measurement error (0.2-0.5°C); the need for periodic fine tuning and calibration of the device, recalibration, recharging and repair; the possibility of measuring temperature just for particular parts of the body (forehead, ears); and fairly high price.[9-11]

We conducted the studies to determine products of which companies manufacturing medical thermometers are presented on our domestic market. The results are given in Table 2.

The total number of records in the State Medical Register of Medical Equipment and Medical Devices is 21.[6]

The marking, packaging, transportation, and storage of thermometers should be carried out according to DSTU EN 980: 2007 graphical symbols for the marking of medical products (EN 980: 2003, IDT).[12]

On each thermometer, there should be affixed the trademark of the manufacturer; number of the thermometer according to the numbering system of the manufacturer; and unit of physical value "°C."

General requirements for a package of medical thermometers:

1. A document indicating: Name and type of the thermometer; number of thermometers; date of manufacture; and designation of this standard should be attached to each box with the thermometers
2. Each thermometer must be packed in a cardboard or plastic case with a shock-absorbing gasket
3. The thermometers in tubular casings should be laid down in the tare in between layers of wooden shavings inside solid board boxes Types II and III
4. The weight of the box with the packed products should not exceed 50 kg.

The technical requirements for medical thermometers are regulated by DSTU ISO 1771: 2006 general purpose thermometers with a nested scale (ISO 1771: 1981, IDT).[13,14]

The thermometers are manufactured in accordance with the requirements of the standard for a specific type and calibrated in degrees Celsius (°C) on the International Practical Temperature Scale.

The commodity expert analysis of medical thermometers includes six stages:

- Stage 1: Checking the compliance of the shipping documents;
- Stage 2: Presence/absence of visible damage to the packaging;
- Stage 3: Checking the merchandise appearance and completeness of medical thermometers;
- Stage 4: Organoleptic control and testing of the functional properties of medical thermometers;
- Stage 5: Registration of a written permit for the sale of goods;
- Stage 6: Sale (storage) of medical thermometers.

Table 2: An overview of medical thermometers that are presented on the pharmaceutical market of Ukraine by manufacturers

Type of thermometers	Model and manufacturing company for these devices
Mercury thermometers	"IGAR" (W.H.G Medical Equipment Co., LTD by order of the firm "Игар," Ukraine); "СКЛОПРИЛАД" (Ukraine); "Импэкс-мед" (Russia); Gamma T 50, Gamma (Taiwan); Medicare MC - RT (Great Britain); PARAMED (Wuxi Medical Instrument Factory, China); Wuxi Medical Instrument Factory (China)
Alcohol thermometers	Wuxi Medical Instrument Factory (China); PARAMED (Wuxi Medical Instrument Factory, China); H Dr House (Zhoushan Tongxin Instruments Co., Ltd., P. R. China)
Infrared non-contact thermometers	Hebei Create (China); HM Digital Inc. (THE USA); Baby Ono 116 (Poland); Maniquick MQ150 (Switzerland); CITIZEN CT - 461C; OMRON Eco Temp Basic; OMRON Flex Temp Smart (Japan); ARZUM BEBBE THERMOMETER (Turkey); One Second here HoMedics (design: USA, made in China); Medisana CL 76120 (Germany); child's Topcom TH 4655 (Holland); multifunction Topcom TH - 4655 (Belgium)
Electronic thermometers	"Склоприлад" (Ukraine); GAMMA (Hangzhou Universal Electronic Co., Ltd., China); OMRON (Japan); Gamma Thermo Soft, Gamma Thermo Base (Great Britain)); Dr. Frei, Microlife of MT-3001 (Switzerland); AAR - PRO (TaiDoc Technology Corporation, Taiwan); VEGA MT J18 - BC (Great Britain); Vega MT418-BC (Germany); Terraillon 06548 (France); Meditech AMDT - 12 (Japan); Little Doctor LD - 300 (Singapore); Bremed BD1130 (Italy); LONGEVITA MT - 4218 (Great Britain); AEG FT 4904 (Germany); MEDICARE MPTI 025; DT - 806 C, Heaco (Great Britain); Medisana FTF (Germany); Beurer FT 09 (Germany); Vipose of iFever (China); iTherm (Japan); "IGAR" (Hangzhou Hua'an Medical & Health Instruments Co., Ltd., China)

Table 3: Algorithm of actions in case of disinfection of the premises in the event of mercury thermometer damage

Position number	Table of contents of works
1	For all those present on the premises, the wet gauze bandages on the nose and mouth should be prepared, as well as medical rubber gloves and shoe covers on the footwear. Without these protective means, no one is allowed to go into the room where the mercury thermometer was broken
2	Prepare a container with water, where all used materials should be put down when cleaning the place of contamination
3	Prepare tissue or napkins soaked in oil or water; prepare sticking patches or adhesive plaster – small droplets of mercury and small scoops of glass stick well onto them
4	Prepare a rubber syringe (which should be then also disposed of) or a disposable syringe - they are very convenient to "suck in" the mercury droplets from the cracks in the floor
5	Prepare a brush wetted in water – to push out small particles of mercury from the deep slits in the floor
6	Prepare a flashlight to see the smallest particles of mercury in the small slits and cracks
7	Prepare a bucket with a liquid for demercurization: A concentrated solution of potassium permanganate, or a concentrated solution of chlorine lime, or a solution of a mixture of 40.0 g of soap, 30.0 g of soda per liter of water. Thoroughly treat the floor and other places where the mercury thermometer has crashed
8	Prepare soft cloth or non-woven napkins to wipe the surface, wetting them with a deactivating fluid and dense plastic bags, where the used materials, brushes, and gloves should be put in then
9	Remove droplets of mercury and treat the floor with the liquid for demercurization (Stage 7). Ventilate the room. All wastes and consumables should be wrapped in dense polyethylene bags and placed at special disposal spots for hazardous waste

Although mercury thermometers represent a dangerous device in the event of damage, then in such cases, measures should be taken to prevent mercury vapor from poisoning. We propose an algorithm of action for neutralization of the released mercury from a broken thermometer [Table 3].

It is advisable, after self-cleaning, to call on specialists who can make certain that the concentration of mercury vapor in the room does not exceed the admissible standards, and if necessary, conduct appropriate demercurization of the room. All consumable materials collected in dense polyethylene bags in the process of cleaning can never be dumped into trash cans. The disposal of the waste hazardous for human health is carried out by special demercurization centers.

CONCLUSIONS

According to the results of the study of the commercial product range of medical thermometers, we found out that the widest and most diverse commercial product range of thermometers in Ukraine, in terms of functionality, was represented by foreign manufacturers of these devices. Based on the analysis of the Ukrainian market, it was established that the dominant positions in the range of medical thermometers were occupied by foreign manufacturers from China, Japan, USA, Great Britain, and Germany. Ukraine needed to improve its own research in the field of development of new types of this product, as well as to take over the experience of foreign manufacturers regarding the variety of additional functions for thermometers, their range, and methods of their manufacture.

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