SPECIAL ASPECTS OF THE DRUG MANUFACTURING IN THE MEDICAL ORGANIZATIONS' COMPOUNDING PHARMACIES WITHIN THE LEGISLATION IN EFFECT OF THE RUSSIAN FEDERATION

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Structural and functional changes in a field of medicinal products transacting over the last decades led to a sharp reduction of the manufactured inside the pharmacy products due to the closure of production departments and, in general, production pharmacies in the Russian Federation (RF). According to the data of Federal Service for Surveillance in Healthcare ('Roszdravnadzor'), the share of pharmacies of state and non-state forms of ownership in medical organizations engaged in the manufacture of extemporal drugs in Russia is 6% of all pharmacies [3].

The legislation of the Russian Federation divides the concepts of "production of medicines" and "pharmaceutical activities". In accordance with Federal Law No. 61 [1], pharmaceutical activity is an activity that includes wholesale of medicines, their storage, transportation and (or) retail sale of medicines, their leave, storage, transportation, and the manufacture of medicines. Pharmaceutical activities are carried out by pharmacy organizations that have a license for pharmaceutical activities.

Manufacture of medicinal products - activity on manufacture of medical products by organizations - manufacturers of medical products at one stage, several or all stages of the technological process, as well as storage and sale of manufactured medicines. The manufacture of medicines means the manufacture of medicinal products by pharmacy organizations that have a license for pharmaceutical activities, is carried out in pharmacy organizations according to the requirements coming from medical organizations in accordance with the rules for manufacturing and dispensing medicinal products. From the combined meaning of the law, it follows that the subject of the manufacture of medicines is not a product, but a service for obtaining it, the result of which is a medicinal product for medical use.

When a medical organization receives a request from a pharmacy organization (a document of the prescribed form that is issued by a medical worker entitled to do so and contains instructions from the pharmacy organization for manufacturing and about leave to provide the medical process for the medicinal product), the process of manufacturing the medicinal product is carried out.

It is not allowed to manufacture pharmaceutical companies that have a license for pharmaceutical activities, finished medicines registered in the Russian Federation, and mass production of medicinal products is also prohibited. As examples, we can mention the following medicines manufactured only in pharmacies: 0.5% of potassium iodide solution does not have a factory analog, the inclusion of a stabilizer is impossible, since the drug is used for newborns; Solutions for electrophoresis: novocaine 1% -5%, ascorbic acid 5%, nicotinic acid 0.5%, inadmissible replacement with injection preparations of industrial production; Chlorhexidine bigluconate solution 0.02%, 0.05% sterile (non-sterile solution is produced by industry, while replacement with an unsterile solution is unacceptable - it is used in surgery to rinse cavities during surgery).

Manufacturing is carried out from pharmaceutical substances included in the state register of medicinal products for medical use.

The manufacture of medicines in the pharmacy rests with the pharmacist or a pharmacist-technologist. Auxiliary operations are performed by the packer. Before the manufacture of medicines, quality control of pharmaceutical substances is carried out. Acceptance control consists in checking incoming pharmaceutical substances for compliance with the requirements for indicators: "Description"; "Packaging"; "Marking"; In the verification of the availability of documents confirming the quality of medicines. For pharmaceutical substances used in the pharmacy manufacturing of medicinal products, in accordance with the legislation should be the following documents: quality certificate (passport) of the substance manufacturer; Test report on indicators: "description", "packaging", "marking"; Availability of registration certificate.
Control over the indicator "Description" includes checking the appearance, color, smell. When checking the "Packaging" indicator, special attention is paid to its integrity and compliance with the physico-chemical properties of medicines. When controlling the "Marking" indicator, attention is paid to the compliance of registration of medicines with the current legal requirements [4].

Manufacturing is carried out in the assistant room, while the joint manufacture of dosage forms for internal use and medicinal forms for external use is not allowed. The area of the assistant room depends on the size of the recipe, the number of pharmacists and packers, and the availability of an analytical pharmacist. The assistant room communicates with the prescription, material room, the workplace of the pharmacist-analyst and washing-sterilization.

In a separate room (aseptic unit), solutions for injections and infusions, eye drops, ophthalmic solutions for irrigation, all solutions for newborn infants, individual solutions for external use are manufactured. The premises of the aseptic unit should be located in an isolated compartment and exclude the crossing of "clean" and "dirty" streams. The aseptic unit must have a separate entrance or be separated from other premises by the locks. Before entering the aseptic block is a gateway. In the airlock: a bench for re-training with cells for special footwear, a cabinet for dressing gown and sterilizing drum with sets of sterile clothes; Sink (tap with elbow drive), air electric dryer and mirror; Hygienic set for hand treatment. The supply and exhaust ventilation is created, in which the movement of air flows is directed from the aseptic unit to the adjacent rooms, with the predominance of air inflow over the hood. Change of sanitary clothing is made at least 2 times a week, towels for personal use - daily [2]. A set of special clothes for personnel who perform sterile production in aseptic conditions before starting work. Due to technological difficulties and a high risk of undesirable reactions, as a rule, such forms are made by a pharmacist-technologist.

After manufacturing, all medicines (including homeopathic) are subject to intra-pharmacovigilance control: written, organoleptic and control during release - mandatory; Interrogatory and physical - selectively; Chemical treatment of certain groups of medicinal forms (purified water, water for injections daily, all medicines, concentrates and semi-finished products (including homeopathic tinctures, triturations, solutions, dilutions) coming from the storage rooms to the assistant room, and in case of doubt - medicines entering the pharmacy from the warehouse, concentrates, semi-finished products and liquid medicines in the burette installation and in the barrels with pipettes in the assistant's room during filling, as well as industrial produced drugs, prepacked in a pharmacy, and intra-pharmaceutical preparation, manufactured and packaged in a pharmacy (each series)).

Control during the holiday is subjected to all manufactured medicines (including homeopathic). The given control consists in check

of conformity of packing to physical and chemical properties of medicinal substances; Registration of medicines to the current requirements. At holiday special attention paid to the design of the appropriate warning labels manufactured in pharmacies of drugs for medical institutions. For solutions for medical enemas, a warning label "For enemas" should be attached; on solutions for disinfection - the inscription "To disinfection", "Handle with care", all drugs which are released in the pediatric departments of medical organizations, the word "Pediatric".

Perform quality control of the medicines manufactured in drugstores, only authorized specialist with the highest pharmaceutical form - specialist analyst having a certified specialist in "Pharmacognosy and pharmaceutical chemistry" (given the presence of a shortage of such specialists in the labor market [6].) After the quality control of medicines, the pharmacist-analyst puts on the passport of the written control the analysis number and his signature. The results of quality control of drugs recorded in the logs on the established forms (log of the results of the organoleptic, physical and chemical control of the produced drug, forms manufactured according to individual prescriptions (requirements of medical institutions), concentrates, semi-trituration, ethyl alcohol and packing; log The results of the control of "purified water", "water for injection", a journal of the results of control of medicines on the base identification; log of the individual manufacturing steps solutions of test results for injections and infusions; log acquisition mode starting sterilization of drugs, medicaments manufactured, auxiliary materials, utensils, etc.).

After the quality control of medicines made-made storage according to their physical and chemical properties and requirements of State Pharmacopoeia of Russia, applicable regulations, after which they are dispensed into the compartments for use in the treatment process. Drugs from pharmacies are only released to authorized medical personnel.

The departments of medical organizations do not allow the manufacture of medicines, packaging, movement from one container (packaging) to another and the replacement of labels. Medicines shall be stored in offices only in the original pharmaceutical packaging. The commission consisting of employees of the pharmacy, senior and senior nurses of the medical organization carries out constant monitoring in the departments for observing the storage conditions of

the manufactured medicines, their proper and rational use, monitoring the occurrence of undesirable reactions.

Conclusions

1. In the Russian Federation only 6% of pharmacies in medical organizations produce medicines.
2. Manufacture is carried out in pharmacies according to the approved rules on the basis of a special document - the requirements of the medical organization.
3. It is not allowed to manufacture medicines registered in the Russian Federation by pharmacy organizations that have a license for pharmaceutical activities, as well as serial production of medicinal products.
4. Groups of medicinal products have been identified, the replacement of which by industrial analogs is unacceptable, or such analogs do not exist.
5. Features of manufacturing of injection and infusion medicinal forms are analyzed.
6. Content analysis of literary data, regulatory and legal framework, revealed a list of preventive measures that ensure the high quality of manufactured medicines, their safety: compliance with sanitary norms and regulations; Anti-epidemic regimen, as well as conditions of aseptic manufacturing in accordance with the current regulatory documents; Rules for obtaining, collecting and storing purified water, water for injection; Maintenance of serviceability and accuracy of devices, devices and a weight economy, regularity of their check; Implementation of acceptance control of incoming pharmaceutical substances and pharmaceuticals; compliance with the technology of the manufacturing process of medicines.

REFERENCES

1. Федеральный закон от 12.04.2010 № 61-ФЗ «Об обращении лекарственных средств».
2. Приказ Минздрава России от 16.07.1997 г № 214 «О контроле качества лекарственных средств, изготовляемых в аптеках».
3. Реестр лицензий Федеральной службы по надзору в сфере здравоохранения

[URL:http://www.roszdravnadzor.ru/services/licenses, дата обращения: 28.11.2016].
4. Глембоцкая Г.Т., Бахарева А.В. Организационно-правовые аспекты использования фармацевтических субстанций в аптечном изготовлении лекарственных препаратов//Health and social Care Journal, № S1 (1), 2015. P. 30.
5. Пичугина, В.В. Фармакобезопасность - обязанность компаний и врачей. Актуальность, предпосылки к развитию и становление / В.В. Пичугина, И.С. Аносов // Медицинская этика. – 2015. – № 1. – С. 94-97.
6. Плутницкий А.Н. Совершенствование кадрового обеспечения муниципальных больничных учреждений // Проблемы социальной гигиены, здравоохранения и истории медицины. – 2013. – № 1. – С. 38-42.