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ORIGINAL ARTICLES

Medical devices in current medicine

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Abstract: *The treatment of diseases is based on pharmacological and non-pharmacological means, but adequate devices are needed for their application. Medicine uses a wide range of medical devices. Currently, many medical devices are used, many of them being disposable. As recognition of the importance of medical devices, the national authority of the drug is the ANMDM (National Agency for Medicines and Medical Devices).*

Medical devices are indispensable for therapy, and their evolution has led to an extraordinary diversification of the field and the emergence of industry related to the pharmaceutical industry, with specific laws and regulations.

Keywords: *medical device, medicine, pharmacological action, non-pharmacological action, health legislation*

INTRODUCTION

The treatment of diseases is based on pharmacological and non-pharmacological means, but for whose application different devices are needed, suitable physical objects, without which treatment cannot be applied. Modern medicine uses a wide range of medical devices, some derived from classical forms, and others that are new and more complex, which revolutionize therapy. Although their use is very old, the term as such has been newly introduced in medical terminology, from the English terminology medical device. Another neologism, related to this, is disposable = available, which, together with a noun, also means "disposable". Currently, many medical devices are used, either small or large, simple or complex, many of them being disposable. As a recognition of the importance of medical devices for the medical and pharmaceutical field, as well as for the medical and pharmaceutical industry, the current national authority of the medicines (not a drug, apud WHO) has been renamed the ANMDM (National Agency for Medicines and Medical Devices) [1, 2].

GENERALITIES

Definition: "Medical device" means any instrument, apparatus, machine, appliance, or other item used alone or in combination, including the software necessary for its correct application, intended by the manufacturer to be used for human beings, and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of the pain,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- the investigation, replacement, modification, or support of

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the anatomy or a physiological process,
- control of conception (Law 176/2000).

Legislation

The specific legislation, including regarding medical devices, also appeared later on - in 1976, the Regulatory System for the MD - US. In 1993, the EU Regulatory System 93/42/EEC and Romania: Law 176/2000 on medical devices and Law 434/2004, with the Government Decision and Orders of the Ministry of Health. Example: HM Order 253/2010 regarding the reclassification of medical devices and 75/2010 for the Rules for Good Pharmaceutical Practice.

Within the HM, operate specific structures such as the Commission for Medical Devices and the National Agency for Medicines and Medical Devices. We mention that in the European Union, the pharmaceutical field was removed from the Health and included in the Industry, which caused some controversy in the medical world [3-23].

Authorization

Medical devices can only be marketed if they are effective, meet the intended purpose, and ensure patient safety. The certificate of conformity issued by the manufacturer guarantees the attestation of the product for being placed on the market and the classification in the corresponding risk class. The inscription must comply with the European Conformity Marking "CE" (conformitè europèene), which allows free movement in the EU space and should not be confused with "C E" (China Export), which has a space between letters. It turns out that a new medical device, being a product of the scientific research of development-innovation, will go through the following stages: Experimental model, Functional experimental model, Prototype (technological demonstrator), and zero series (at the manufacturer). The technical file of a medical device, which is subject to the approval of the NAMMD, contains information regarding the: device description, type of raw materials used for manufacturing, stability study, analysis bulletin, validation, description of the packaging, and instructions for use. The serial products must be manufactured with the technical assistance of those who have the patent for the product.

CLASSIFICATION

There are many types of medical devices and they can be classified according to several criteria:

1. Risk level
- Class I, Low risk: non-invasive medical devices (eg patches, bandages) and invasive (eg surgical gloves);
- Class II, Medium risk (use 1h-30 days) invasive (eg needles, catheters);
- Class II b, potentially high risk (use - more than 30 days) invasive (eg: probes, devices for repeated administration) and non-invasive (eg: modern dressings that come in contact with the damaged skin);
- Class III, High risk: surgically invasive, a tissue of animal origin, implantable or an integral part of a drug (eg dressings with antibiotics).

2. Access path
- Urinal,
- Digestive,
- Surgical,
- Respiratory,
- Parenteral.

3. Duration of use
- Transitional action, less than 1 hour,
- Short term, less than 1 month,
- Long term, over 1 month.

4. Frequency of use
- Single-use,
- Repeated,
- Permanent,
- When necessary.

5. Impact on the body
- Non-invasive,
- Invasive,
- Surgically-invasive,
- Implantable.

6. Method of manufacture
- Sterile (disposable or re-sterilizable),
- Nonsterile/aseptic.

7. Mode of operation
- With power source (eg electric battery),
- Without a power source.

8. Place of use
- Medical institution,
- Home,
- Portable.

After use in different activities:
Medical devices for:
- Diagnosis and monitoring,
- Administration of medicines,
- Parapharmaceutical (ex: dressings),
- Damaged tissue (orthopedics, surgery, burns),
- Oral hygiene,
- Sexual protection,
- Childcare,
- Medical imaging.

Categories of users:
- Manufacturing companies,
- Suppliers and distributors,
- Sanitary units,
- Medical technical workshops,
- Patients and clients.

QUALITY

The quality requirements are set out in the specific Reference Standards. Starting with 01.03.2019, ISO 13485: 2016 is mandatory. This standard is designed for organizations involved in the design, production, installation, and maintenance of medical devices and for risk management.

• Sterility

All devices and technical-medical products that come into direct contact with tissues and biological fluids are required to be sterile.

Sterilization by heat, gas, or radiation is chosen depending on the nature of the material to be sterilized and the efficiency of sterilization is checked according to FR X unless otherwise provided.

• Storage

The storage and transport of medical devices are done according to the general provisions of FR X unless otherwise provided. Some materials must be stored under special conditions: rubber, plastics, metal tools, dressing materials, and utensils.

LABELING

Markings

Medical devices must be labeled, on the product, on the packaging and the instructions for use with the information essential to the safety of the user:
- The product's name,
- Identification of the manufacturer,
- Lot number and series, including the date,
- Storage conditions,
- Method of operation.

In some cases, additional data is required for special labeling:
- Sterile,
- Disposable,
- Exclusively for clinical investigations;

Different graphic symbols or warnings can be added.

RISK MONITORING

The safe handling of health products is called vigilance:
- Pharmacovigilance for pharmaceuticals and pharmaceutical raw materials,
- Materiovigilance for medical devices,
- Reacto-vigilance for in vitro diagnosis,
- Biovigilance for temporary-use cellular products,
- Hemovigilance for blood products.

Materiovigilance pursues the incidents arising from the use of the technical-medical products, to ensure the safety of the medical procedures, permanent monitoring of the incidents, and the risks of their occurrence. On the Materiovigilance Data Sheet are reported the essential information related to erroneous indications, omissions, or incomplete instructions. On their basis, studies and expertise are also carried out for the continuous evaluation of the risk level after being launched on the market.

RAW MATERIALS AND PACKAGING

The raw materials can be natural or artificial, single or in combinations: cellulose, cotton, metals, and alloys, natural and synthetic rubber, ceramic materials, glass, plastics, etc. or combinations thereof. All materials used must be compliant for medical use, from pharmaceuticals to the finished product, including packaging. As an example, medical devices for the application of innovative antibacterial and/or antibiofilm drugs fall within the general definition, according to the legislation in force. They must meet all the conditions for authorization, both as a package and/or applicator, and as a medicine administered for the treatment of the patient; they must come accompanied by a Technical File, Analysis Report, and a Conformity Certificate endorsed by the HM through the NAMMD. They fall into Class II b of Potentially High Risk, non-invasive as modern dressings, which are exposed to damaged skin or Class I Low risk, non-invasive. All components must be sterile or aseptic and must be stored and used properly. The labeling must be complete, accompanied by the appropriate markings and with the follow-up on the Materiovigilance. The pharmaceutical forms and the packages (applicators) in which they can be presented may differ, depending on the particularities of the treatment, being required several experimental models for choosing the prototype. Each of the components must come accompanied by a medical opinion for use, and if it does not, it must be requested from the NAMMD, which means time and money for taxes [3, 4, 9, 12].

As examples of medical devices for the application of pharmacologically active drugs may be listed the following:

1. Paper sachets, amylaceous, etc.
2. Capsules: soft or hard, gastro-soluble or gastro-resistant, with compartments or concentric (delayed), etc.
3. Pencils: liquid or powder dosage, etc.
4. Ampoules: glass or plastic, brittle, compartmentalized (lyophilized powder and solvent).
5. Bottles: glass or plastic, perforable, dropper, jet, sprayer (passive, active)
6. Bottle/dose atomizer under pressure (spray)
7. Patches: fast or delayed (for different areas) etc.
8. Implants: in an orifice, subcutaneous, submucosal, and visceral (eg: ovules, suppositories, spark plugs, cones, etc.)
9. Impregnated dressings: solutions, powders, solubles, ointments, absorbable or non-absorbable, hydrogel, etc.

COMMENTS

Currently, our research team is studying medical devices for the application of pharmacologically active drugs, for the substitute, adjuvant or complementary treatment to the anti-infective treatment, especially against resistant bacteria.

There are different medical devices, suitable for types of substances and dosages, authorized for medical use, from which we can choose the most suitable for the purpose; creating a new device, simple or complex, would require a complicated and costly procedure, but unnecessary in this case. The range of medical devices that can be filled with the appropriate pharmaceutical preparation is currently provided by the pharmaceutical industry upon request.

By combining the newly proposed drug with the chosen medical device, experimental model variants are achieved [24]. After experimenting with these under different conditions, the functional experimental model is obtained, as a masterful and/or galenic pharmaceutical preparation for the testing provided by the Law on medicinal products, and will subsequently enter under the pharmaceutical authorization procedures.

CONCLUSIONS

Medical devices are indispensable for therapy, pharmacological, or non-pharmacological. Their evolution has led to an extraordinary diversification of the field and the emergence of industry related to the pharmaceutical industry, with specific laws and regulations. Medical devices play a very important role in modern medicine.

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