Approved from the Faculty council with protocol: 3/04.05.2022 г.

DEAN:
/prof. Al.Zlatkov, DSc/

DEPARTMENT "ORGANIZATION AND ECONOMICS OF PHARMACY"

SYLLABUS
of
PEDIATRIC DRUG FORMS – elective subject

INCLUDED IN "P**HARMACY**" EDUCATION CURRICULUM
DEGREE OF EDUCATION: "**MASTER**"
CREDITS (ECTS): 5

ANNOTATION

Children are often excluded from most studies on the effect and need of specific drugs for reasons such as ethical implications of including them in educational programs and studies, methodological problems, obtaining unreliable data due to age characteristics. Studies of the effects and attitudes towards drug therapy are conducted indirectly by taking the opinion of parents/guardians and refracting the results through their lens. On the other hand, the creation and production of age-specific dosage forms is an important technological problem. Despite the well-known fact that "the child's organism is not a reduced copy of the adult", and that age affects the metabolism, absorption and excretion of drugs, still the number of medicinal products created specifically for children, both in our country and globally it is very small. The younger the child, the more difficult it can be to find a suitable dosage form for him. The safety of medicinal products for children is also an important issue and legislative requirements in this

area have been changing in recent years at the European level. The Regulation of the European Parliament and the Council of the EU (No. 1901/2006) on medicinal products for pediatric practice defines in detail the legislative issues for the conduct of clinical trials in children, the authorization and production of medicinal products for pediatric practice. In the same year, the concept developed by EMEA for creating "appropriate medicines for children" (Vetter medicines for children, 2006) was published, which requires the development of specific medicinal forms for pediatrics. The strategy emphasizes the risk that medicinal forms that are not adapted to the peculiarities of the child's organism cannot guarantee the achievement of an optimal therapeutic effect of the included medicinal substances. Compliance with the doctor's prescription is also an important problem. The rate of non-compliance in these patients is about 40 to 50%, and there are even literature data that in some cases it reaches 75%. In children, a complex manifestation of all causes of non-compliance is observed. Non-compliance is primarily due to the impact of the following factors: ⦀ lack of knowledge regarding the regime of compliance and taking medicines; ⦀ low motivation to comply with the medication regimen; ⦀ disproportionately high uptake of prescription and non-prescription drugs from the attending physician; ⦀ frequent change in the dosage and time of taking the medicine without consultation with the attending physician. The basic training of the cold ones in pharmacy gives them knowledge about the type of dosage forms, but it does not go into the details of the age-dependent features in their creation, and the changes in the legislation definitely make it necessary to expand the knowledge of the interested students in this direction. Part of the topics included in the SID program are dedicated to the various pharmaceutical forms intended for pediatric practice. The specific features and requirements for their creation, preparation and application are outlined. The proposed course also emphasizes the peculiarities of interpersonal relationships, the importance of perception, barriers that prevent communication, in children, their parents and adult patients. The program also includes specific case studies for the acquisition of practical skills that facilitate communication between the pharmacist and the patient (or his relatives). Particular attention is paid to strategies to improve patient compliance with their treatment.

English language training

SYLLABUS

1. Historical foundations of the creation of pediatric dosage forms.
2. Legal framework for children's rights - international legislation
3. Legal framework for children's rights - Bulgarian legislation
4. Legal basis for conducting clinical studies in children

5. Specificity of rational medicinal use in children

6. Nature and measurement of compliance and adherence in children

7. Medical devices for dosing and administration of medicinal products in children - specifics, requirements, measurement

8. Specificity of the child's organism during the different age periods

9. Children's medicinal forms - current state, problems and perspectives Peculiarities of children's dosage forms - specific requirements and approaches in optimizing drug therapy

10. Dosage forms for oral administration - liquid dosage forms. Specific requirements of liquid dosage forms in pediatrics.

11. Pharmaceutical forms for oral administration - solid dosage forms. Specific requirements for solid dosage forms for children in pediatrics.

12. Medicinal forms for application on the skin - specific requirements, possibilities, approaches and limitations

13. Pediatric dosage forms intended for alternative routes of administration (pulmonary, nasal, buccal, oromucosal) - general characteristics, requirements, limitations and perspectives.

14. Orodispersible tablets and orodispersible films in pediatric practice

15. Application of 3D printing in pediatrics - opportunities, approaches, limitations and perspectives.

Date ..... Program authors:

/Team of Department “Organization and economics of pharmacy/and form the Department Pharmaceutical technology and biopharmacy

Head of Department “Organization and economics of pharmacy”

/prof. Maria Dimitrova, PhD/