Questions for the exam promotion at
MANAGEMENT AND PHARMACEUTICAL LEGISLATION
included in the assessment no.2, for 4th year students, 2019-2020

1. Classification of products issued from the pharmacy.
2. The importance of medicines and their specific features.
3. The main stages of drug development.
4. Good Laboratory Practice (GLP) and their impact on the safety, efficacy and quality of medicines.
5. Good Clinical Practice (GCP) and their impact on the safety, efficacy and quality of medicines.
6. Good Manufacturing Practice (GMP) and their impact on the safety, efficacy and quality of medicines.
7. Good Distribution Practice (GMP) and their impact on the safety, efficacy and quality of medicines
8. Good Pharmacy Practice (GPP) and their impact on the safety, efficacy and quality of medicines
9. Nomenclature and classifications of medicinal products.
10. Essential medicines
11. Principles of storage of medicinal products and groups of medicines classified according to these principles.
12. Indicate the rules of storage of photosensitive medicines. Examples.
13. Indicate the rules of storage of hygroscopic medicines. Examples.
14. Indicate the rules of storage of volatile medicines. Examples.
15. Indicate the rules of storage of crystal hydrates. Examples.
16. Indicate the rules of storage of thermolabile medicines. Examples.
17. Indicate the rules of storage of medicines, which should be protected from the effects of low temperatures. Examples.
18. Indicate the rules of storage of aromatics and colorants. Examples.
19. Authorization of medicines. Purpose of authorization.
20. Steps, principles and criteria for the authorization of medicinal products.
21. State Nomenclature of Medicines

22. Documentation for the marketing authorization of medicinal products.
23. The Marketing Authorization (certificate of registration) of medicinal product, the issuance and content.
24. The Medicines Committee and its role in the authorization of medicines.
25. General requirements for the manufacturing of medicinal products.
26. Technological documentation of medicines manufacturing.
27. The general feature of the medicine delivery system. Supply cycle.
28. Authorization of import in the Republic of Moldova
29. Contracts of supply and delivery of pharmaceuticals.
30. The pharmaceutical warehouse, its tasks and functions. The organizational structure.
31. Requirments for premises and equipment of pharmaceutical warehouse.
32. Principles of storage of medicines in the pharmaceutical warehouse.

33. The rules for receiving pharmaceutical products from suppliers.
34. Pharmaceutical legislation on the protection of rights of consumers of medicines.
35. The general characteristic of the quality assurance system for medicinal products.
36. Task and functions of the Laboratory for Quality Control of Medicines.
37. State Quality Control of Medicines.
38. Types of state control of medicines and their feature.
39. Documentation on the quality of medicines.
40. Surveillance and pharmacovigilance of medicinal products. Monitoring of adverse reactions.
41. The characteristic of pharmaceutical assistance system. Basic principles of organizing the activity of community pharmacies.
42. Principles of location and extension of the pharmacy network in Moldova.

43. Types of pharmacies. Public access (community) pharmacy. The foundation of the pharmacy, its task and functions.
44. Requirements for the premises of the pharmacy and the location plan, the equipment.
45. Sanitary regime in the pharmacy: sanitary requirements for rooms and equipment.
46. Sanitary regime in the pharmacy: sanitary requirements for the cleaning of the rooms and the pharmaceutical machinery.
47. Sanitary regime in the pharmacy: sanitary requirements for the hygiene of personnel.
48. Sanitary regime in the pharmacy: sanitary rules for the preparation, transport and storage of purified water and injectable water.
49. Sanitary regime in the pharmacy: sanitary requirements for the preparation of medicines under aseptic conditions and non-sterile medicinal forms.
50. The organizational structure of public access pharmacies. Subsidiaries of pharmacies.
51. Pharmacy personnel, nomenclature of specialties and pharmaceutical workplaces. Pharmacy management.
52. Obligations and rights of pharmacists and the documents they are conducting.
53. Employment agreement. Content and order of signing.
54. The material responsibility in the pharmacy and its legalization.
55. Pharmacy manager - the main authority of the company.
56. Managerial jobs in pharmaceutical units.
57. Main aspects of managerial activity in pharmaceutical units.
58. Requirements to the personality of the pharmacy manager.
59. Organizing the work of pharmacist manager.
60. Pharmacist manager - subordinate relationship.
61. Managerial ethics aspects.
62. Ethics and pharmaceutical deontology.
63. Human resources management. Functions of human resources management.

64. General aspects of certification of pharmacists.