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**REQUIREMENTS FOR CONDUCTING A COLLOQUIUM
ON SOCIAL PHARMACY AND PHARMACEUTICAL LEGISLATION
AFTER COMPLETION OF UNDERGRADUATE INTERNSHIP**

INSTRUCTIONS FOR DEVELOPING A SCIENTIFIC ESSAY

The scientific essay is a written work that has a volume of 5 to 10 standard pages. It is compiled on an explicitly set, specific topic, which covers part of the curriculum. It is organized in three parts - introduction, presentation and conclusion. The text presents facts, theses, positions, theories and it is required to indicate the references at the end of the essay. It is formed technically according to the specified requirements. The paper must be submitted on paper on the day of the colloquium on "Social Pharmacy and Pharmaceutical Legislation".

TECHNICAL REQUIREMENTS FOR FORMATION OF ABSTRACTS

I. LAYOUT

1. Title page

- Author and Affiliations (e.g. university, faculty, department, faculty number)
- Title: The title should be capitalized
- Supervisors` names and signatures

Sample title page of an essay

**MEDICAL UNIVERSITY – PLOVDIV
FACULTY OF PHARMACY**

Department of Pharmaceutical sciences

**ESSAY
OF
SOCIAL PHARMACY AND PHARMACEUTICAL LEGISLATION**

TOPIC
THE CONCEPT OF GENERIC DRUGS AND BIOEQUIVALENCE

Prepared by:

Reviewer:

Plovdiv, 2022

2. Design a content page

Starts on a new page after the title page. Includes the introduction, all parts of the exposition, conclusion and references. The page numbering starts from the introduction.

CONTENT *(Example)*

INTRODUCTION

- 1.
- 1.1
- 1.2.
- 2.....
- 2.1.
- 3.
- 3.1.....
- 3.2.....

CONCLUSION

REFERENCES

3. Page format

Spacing, Fonts, and Page Numbering

The text is arranged in 30 lines per page.

- The main parameters of each page should be as follows:
- **Paper size:** File, Page Setup, Paper Size – A4.
- **Font:** Times New Roman, 12 pt.) , Regular
- **Line spacing:** 1,5 lines;
- **First line:** 1,25 cm;
- **Print area:** top – 2,54 cm; Bottom – 2,54 cm; left– 3,5 cm; right –2,5 cm
- **Footnotes:** Times New Roman, 10 pt., line spacing: Single;
- **Main text and footnotes:** Alignment: Justified;
- **Page numbering:** bottom, center right, in Arabic numerals.

4. References

- **Books and Monographs:** List the name or the author(s), title, place or publication, publisher and date.

Example: Kassirer JP, Kopelman RI. Learning clinical reasoning. 2nd Ed. Baltimore (MD): Williams & Wilkins; 2009

- **Websites** - author, title, exact website address and the date on which this information was found.

Example: Medicines under additional monitoring.

https://www.ema.europa.eu/en/documents/additional-monitoring/list-medicinal-products-under-additional-monitoring_en-0.pdf (Accessed: 20 February 2022)

- **Scientific articles** - author, title, journal, year, edition, page.

Example: Hoekman J, Boon WP, Bouvy JC, Ebbers HC, de Jong JP, De Bruin ML. Use of the conditional marketing authorization pathway for oncology medicines in Europe. Clinical Pharmacology & Therapeutics. 2015;98(5):534-41.

- **Information from scientific conferences** - author, topic, title and place of the conference, date.

Example: Staynova R, Andreevska K, Grekova D, Gueorguiev S, Madzharov V, Bratanov P. The impact of pharmaceutical care on patients with cancer. Scientific conference "15 years of Pharmacy in Medical University of Plovdiv" 01-03 June 2018, Devin

5. Print the essay

The scientific essay should be printed in A4 format.

The sheets can be connected in a plastic spiral or in a folder.

II. REQUIREMENTS FOR THE CONTENT OF THE ESSAY

The scientific essay is a review, but it can also be analytical in nature, depending on the specific curriculum. The text is short and concise, and the author must express his position and show knowledge of the subject. The position must be specific - to refer only to what will be discussed in the text and to be supported by relevant arguments.

Introduction

The aim is to present the topic of the paper and its significance. The specific question to be answered is also presented. A working hypothesis can be included here, which will be tested in the course of the presentation, depending on the nature of the paper.

Presentation

The presentation is a logically connected sequence of arguments related to the topic of the paper. The logic of the statement can go from the more general to the more specific, from weaker to stronger arguments, from more well-known to less known evidence. Other strategies are possible, as long as they lead to a convincing presentation of personal information.

Conclusion

It is a summary of the introduction. It must answer the question posed in the introduction. This answer should be logically derived from the statement.

References

Use the Vancouver reference style which is known as the author–number system – it uses numbers in square brackets within the text (in-text citations) that refer to numbered entries in the reference list.

The list of References should be included after the final section of the main article body. The References items should be listed in numerical order, and in the same order in which they are first mentioned in the text (not alphabetically). The reference list should include all and only those references you have cited in the text. Use Arabic numerals (1, 2, 3, 4, 5, 6, 7, 8, and 9) to identify a reference item that is the same as the number cited in the respective in-text citation.

SCIENTIFIC ESSAY TOPICS
OF “SOCIAL PHARMACY AND PHARMACEUTICAL LEGISLATION”

1. Serialization and verification of medicinal products. Counterfeit medicines.
2. Usage of unauthorized medicinal products. Compassionate use.
3. Legislative requirements and regulation of radiopharmaceuticals.
4. Management of the wholesale of medicinal products.
5. Medical devices – placing on the market and legal requirements. Medical devices in hospital and community pharmacy.
6. Good medicine donation practice.
7. Guidelines of Good Distribution Practice.
8. Guidelines for Good Pharmaceutical Practice of FIP/WHO and the Bulgarian Pharmaceutical Union.
9. Responsibilities of pharmacy managers. Strategy for pharmacy development.
10. Regulated professions. Act of the Professional Organization of Master Pharmacists. Recognition of qualifications within the EU and the EEA.
11. E-health and e-prescription in Bulgaria and the EU.
12. Online pharmacy. Online sale of medicines. Medicine vending machines – regulatory requirements.
13. Marketing authorization procedures of medicines. Special procedures – hybrid medicines approval, conditional authorization, authorization in exceptional circumstances, expedited examination.
14. The concept of generic drugs and bioequivalence.
15. Biological, biotechnological and biosimilar medicinal products.
16. Legislative requirements for medicines for the treatment of rare diseases.
17. Post marketing surveillance of the quality, efficacy and safety of medicines after the marketing authorization.
18. Traditional herbal medicinal products and simplified registrations for homeopathic medicinal products: pharmacovigilance.
19. Prescribing pharmacist – history and challenges
20. The pharmaceutical profession in the 21st century – professional status, ethical aspects and challenges.
21. Hospital pharmacy. The role of the hospital pharmacist.
22. Parallel trade of medicinal products.
23. Reimbursement of medicinal products. Role of the NHIF in drug policy.

24. Pharmaceutical marketing - approaches and strategies for segmentation, targeting and marketing positioning of drugs.
25. Clinical trials – regulatory approaches and legal requirements. Guidelines for Good Clinical Practice.
26. Advertising of medicinal products. Legislative requirements in the EU and the USA.
27. The role of international and European pharmaceutical organizations in public health.
28. Safety monitoring of vaccines, biological products and medicines under additional monitoring.
29. Comparative analysis of regulatory framework of community pharmacies in European countries.
30. Methods to analyse medicine utilization and expenditure to support pharmaceutical policy implementation.

Requirements for the colloquium were approved by the Department council with protocol № 03/10.03.2022.

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