University of Belgrade

PHARMACOECONOMIC AND PHARMACEUTICAL LEGISLATION



raculty of Fliatiliacy	PHARMACOECONC		CAND PHARMACEUTICAL LI				
Study programme: Pharmacoo	economic and Pharmaceutic	al Le	gislation				
Course title: Pharmaceutical L	egislation						
Teachers: Petrova I. Guenka, k	Krajnovic M. Dusanka						
Course status: core							
Semester:		Yea	ar of studies: I				
ECTS points: 7 Course code: SFFLO1							
Requirements: none	Requirements: none						
Course aims:							
Acquiring knowledge in the ph	armaceutical legislation area	а					
Understanding of the national	, european and internationa	l pha	rmaceutical legal acts				
Understanding of the rules and	d responsibilities in the healt	th ins	surance				
Course outcomes:							
Acquiring knowledge in the ph practice.	armaceutical legislation area	a. Un	derstanding and application of the	legal acts defining the pharmacy			
Course contents:							
Lectures							
Definition and development of National Drug Policy (NDP). Monitoring of NDP. Development of the pharmaceutical legislation. EU Directives defing the medicines. International organization and theire role in pharmaceutical legislation. Organization and functions of EMA. National legislation. National Drug and Medical Devices Agency - role, aims, .scope. Health insurance and finansing.							
Practical classes							
Practical part consists of practical classes and indipendant analysis in pharmaceutical legislation. The curricula follows the topics covered in the theoretical part. NDP - discussion on the examples from different countries and documents. Results of the NDP monitoring. Analysis of national and international pharmaceutical (e.g. Low on medicines and medical devices, health insurance, etc.)							
Recommended literature:							
1. Current laws and directives covering the pharmaceutical legislation in Serbia							
2. EU laws and Directives							
The total of active learning classes							
Lectures: 30		Practical classes: 15					
Research work: 15			Other forms of teaching: 30				
Teaching methods:							
Methods for delivering the curricula include: lectures, interactive activities, case analysis, panel discussion, tests, on-line teaching.							
Grading system							
Exam prerequisites	Points		Final exam	Points			
Active participation in lectures	5 20	Pra	ictical				
Practical classes	30	Wr	itten	50			
Workshops		Ora	al				
Colloquia							
Seminars							
Other activities							

University of Belgrade Fa

#### Specialized academic study



Faculty of Pharmacy	PHARM	MACOECONO	OMI	C AND PHARMACEUTICAL L		2
Study programme: Pharmad	coeconomic and	d Pharmaceutic	al Le	gislation	L	
Course title: Pharmacoecon	omics 1					
Teachers: Petrova I. Guenka	, Lakic M. Draga	ana, Jelic-Ivano	vic D	. Zorana		
Course status: core						
Semester:			Yea	ar of studies: I		
ECTS points: 8			Со	urse code: SFFLO2		
Requirements: none			1			
Course aims:						
Acquiring knowledge in the	pharmacoecon	omics				
Understanding of the pharm	nacoeconomic a	inalyses and me	ethoo	ls		
Understanding the importar	nce of pharmaco	oeconomic eval	luatio	ons in health		
Course outcomes:						
Acquiring and application o analyses and methods.	f knowledge in	the pharmaco	econ	omics. Understanding and applic	ation of the pharmacoeconor	nic
Course contents:						
Lectures						
Introduction to pharmacoe incremental. Calculating the PE methods - cost minimizat cost benefit analysis.	economics (PE) e cost of treatme tion analysis. PE	. Costs (direct ent. Outcomes E methods - cos	, ind in PE t effe	irect and intangible) - fixed, va - clinical, humanistic and econom ectiveness analysis. PE methods - o	ariables, marginal, opportuna nical. PE methods - cost of illne cost utility analysis. PE methoo	int, ess. ds -
Practical classes						
Practical part consists of pra in the theoretical part: calc effectiveness analysis, applie	ctical classes an ulation of the t cation of the co	d indipendant a reatment costs st utilty analysi	analy s, app s, ap	sis in pharmacoeconomics. The cu plication of the cost minimization plication of the cost benefit analy:	rricula follows the topics cover analysis, application of the c sis.	red ost
Recommended literature:						
1. Bootman J, Townsend R, I 2005	McGhan W. Prir	nciples of Pharn	naco	economics. 3rd Ed. Cincinnati: Ha	rvey Whitney Books Company	;
2. Drummond M, OBrien B, New York: Oxford University	Stoddart G, Tor / Press; 1997	ance G. Metho	ds fo	r the Economic Evaluation of Heal	th Care Programmes. 2nd Ed.	
3. Petitti D. Meta - analysis,	decision analys	is and cost-effe	ctive	ness analysis, 2nd Ed. New York: (	Oxford University Press; 2000	
The total of active learning classes						
Lectures: 30		Practical classes: 15				
Research work: 30			Other forms of teaching: 15			
<b>Teaching methods:</b> Methods for delivering the o	curricula include	e: lectures, inte	ractiv	<i>v</i> e activities, case analysis, panel d	iscussion, tests, on-line teachi	ng.
		G	radir	ng system		
Exam prerequisites		Points		Final exam	Points	
Active participation in lectur	res	20	Pra	ctical		
Practical classes		30	Wr	itten	50	
Workshops			Ora	al		
Colloquia						
Seminars						
Other activities			1			

ΓΙΟΝ



University of Belgrade Specialized academic study Faculty of Pharmacy PHARMACOECONOMIC AND PHARMACEUTICAL LEGISLA				
Study programme: Pharma	coeconomic and Pharmaceutica	al Legislation		
Course title: Pharmacoecon	omics 2			
Teachers: Bogavac-Stanojev	ric B. Natasa, Lakic M. Dragana			
Course status: core				
Semester: II		Year of studies:		
ECTS points: 8		Course code: SFFLO6		
Requirements: Pharmacoec	conomics 1			
Course aims:				
Acquiring knowledge in the	pharmacoeconomics modelling	5		
Evaluation of the informatic	on, articles and studies in the pl	narmacoeconomic field		
Course outcomes:				

Understanding and application of the pharmacoeconomic modelling in the evlaution of the costs and outcomes. Critical evaluation of the PE problems.

#### **Course contents:**

Lectures

PE modelling - importance, aims. Variables to be considered in the model. The most often used models in PE: decision tree, Markov model. Application of the decision tree. Application of the Markov model. Importance of the modelling and its application in pharmacy, laboratory, wholesaler, production and other segments of pharmacy practice. Critical evaluation of the published PE studies (criteria). PE considerations for Republic Institute for Health Insurance. Budget impact analysis.

Practical classes

The curricula follows the topics covered in the theoretical part. Appling the tools that allows PE modeling (TreeAge Healthcare Module, Microsoft Excel). Prepartion of the PE part of documentation for third party payer. Application of the budget impact analysis.

#### **Recommended literature:**

1. Bootman J, Townsend R, McGhan W. Principles of Pharmacoeconomics. 3rd ed. Cincinnati: Harvey Whitney Books Company; 2005

2. Briggs A, Claxton K, Sculpher M. Decision modelling for health economic evaluation, New York: Oxford University Press; 2006

3. Petitti D. Meta-analysis, decision analysis and cost-effectiveness analysis, 2nd Ed. New York: Oxford University Press; 2000

4. Правилик о критеријумима за укључивање/скидање лекова са Листе лекова који се прописују и издају на терет средстава обавезног здравственог осигурања.

The total of acti	ve learning classes
Lectures: 30	Practical classes: 15
Research work: 30	Other forms of teaching: 15

#### **Teaching methods:**

Methods for delivering the curricula include: lectures, interactive activities, case analysis, panel discussion, tests, on-line teaching.

Grading system					
Exam prerequisites	Points	Final exam	Points		
Active participation in lectures	20	Practical			
Practical classes	30	Written	50		
Workshops		Oral			
Colloquia					
Seminars					

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#### Specialized academic study



Faculty of Pharmacy	PHARMAC	COECONON	IIC AND PHARMACEUTICA	L LEGISLATION	Y
Study programme: Pharmad	coeconomic and Pha	armaceutical	Legislation		.1
Course title: Pharmacoepide	emiology				
Teachers: Bogavac-Stanojev	ic B. Natasa, Ilic V. k	Katarina			
Course status: core					
Semester: II		١	/ear of studies:		
ECTS points: 6		(	Course code: SFFLO5		
Requirements: none					
Course aims:					
Acquiring knowledge in the	pharmacoepidemio	logy			
Evaluating the avilable infor	mation in the pharn	nacoepidemi	ology field		
Managing the work with dat	a base. Understand	ing the pharr	nacoepidemiology methods.		
Course outcomes:					
Acquiring knowledge in the the database. Understanding	pharmacoepidemio g and application of	logy. Critical pharmacoep	evaluation of the pharmacoepide idemiology methods.	emiology information. Ap	plication of
Course contents:					
Lectures					
Pharmacoepidemiologu - de data, calculating the risk - outcomes. Terms: ratio, pro Data source for mortality. E study, cross-sectional study)	efinition ADR, postn pharmacoepidemic portion, rate. Crude Descriptive studies ( I. Blas and type of b	narketing sur plogy analysi e, standardize ecological stu ias in epidem	veilance, finding the information s. Incidence and prevalence - ed and specific rate. Morbidity. E ady, case study, case series). And iology.	n about ADR. Methods fo the differencies. The co Data source for morbidity alytical studies (case-con	<ul> <li>r acquiring</li> <li>rrelation in</li> <li>Mortality.</li> <li>trol, cohort</li> </ul>
Practical classes					
Practical part consists of pra the ADR risk, information ab	ctical classes in phan out ADR, calculation	rmacoepidem n values (risk,	iiology. Pharmacoepidemiology s . probabilty, odds ratio), etc	systems - inclusion, PSUR	, calculating
Recommended literature:					
1. Strom BL. Pharmacoepide	miology. 4th ed. Ch	ichester: Joh	n Wiley & Sons; 2005		
2. Hartzema AG , Porta M, T Books Company; 1998	ilson HH (editors). P	harmacoepid	emiology. An Introduction. 3th e	ed. Cincinnati: Harvey Wh	itney
3. Vlajinac H, Jarebinski M (e	eds). Epidemiologija	a. Belgrade: S	chool of Medicine		
	-	The total of a	ctive learning classes		
Lectures: 15		Practical classes: 15			
Research work: 15		Other forms of teaching: 30			
Teaching methods:					
Methods for delivering the o	urricula include: lec	tures, interac	tive activities, case analysis, pan	el discussion, tests, on-lir	ne teaching.
	I	Gra	ding system		
Exam prerequisites	Ро	ints	Final exam	Points	
Active participation in lectur	res 2	20 F	Practical		
Practical classes	3	30 \	Vritten	50	
Workshops		(	Dral		
Colloquia					
Seminars					
Other activities					
	I	I			

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#### PHARMACOECONOMIC AND PHARMACEUTICAL LEGISLATION

Study programme: Pharmacoeconomic and Pharmaceutical Legisla	tion

#### Course title: Application of statistical methods in pharmacoeconomics

#### Teachers: Bogavac-Stanojevic B. Natasa

Course status: core	
Semester: I	Year of studies: I
ECTS points: 5	Course code: SFFLO4

#### Requirements: none

#### Course aims:

Acquiring knowledge in the statistic, statistical analysis and application and usage of statistical software. Application of the statistical methods on solving the pharmacoeconomic problems.

#### Course outcomes:

Understanding and application of statistical analysis. Application of the statistical packages in solving the pharmacoeconomic problems

#### **Course contents:**

#### Lectures

Descriptive statistic, testing the hypotesis, probability theory, testing the distribution of the data (examples on costs and effects), calculating sample size, choosing sample (randomization), basic statistical methods (t-test, ANOVA, correlation, Chi-square). Basic assumption in probabilistic model.

#### Practical classes

In the practical part of course, student will apply statistical methods in pharmacoeconomic problems. Application of the probabilistic theory on the decision tree, transitional probabilities for Markov model; practical work - application of the basic statistical methods (t-test, ANOVA, correlation and Chi-square) using the Microsoft Excel and on-line statistical programes, application of probabilistic models in sensitivity analysis.

#### **Recommended literature:**

Wayne W. Daniel. Biostatistics: A Foundation for Analysis in the Health Sciences. 9th Ed. Chichester: John Wiley&Sons; 2009
 Andrew M. Jones, Nigel Rice, Teresa Bago d'Uva and Silvia Balia. Applied Health Economics. 1 st Ed. Taylor & Francis e-Library; 2007

The total of acti	ve learning classes
Lectures: 15	Practical classes: 15
Research work: 15	Other forms of teaching: 30

#### **Teaching methods:**

Methods for delivering the curricula include: lectures, interactive activities, case analysis, calculations, tests, on-line teaching.

Grading system					
Exam prerequisites	Points	Final exam	Points		
Active participation in lectures	20	Practical			
Practical classes	30	Written	50		
Workshops		Oral			
Colloquia					
Seminars					
Other activities					

#### Specialized academic study

PHARMACOECONOMIC AND PHARMACEUTICAL LEGISLATION



Study programme: Pharmacoe	conomic and Pharmaceutic	al Le	gislation		
Course title: Health related qua	ality of life				
Teachers: Bogavac-Stanojevic B	8. Natasa				
Course status: elective					
Semester:    Year of studies:					
ECTS points: 4 Course code: SFFLI1					
Requirements: none		•			
Course aims:					
Applying the selection principle	and using the questionnai	re to	measure health related quality of	f life for cost utilty analy	sis
Course outcomes:					
Understanding the concept of H choosing the questionnaire. Un in understanding the cost-utility	nealth related quality of life derstanding basic statistica y analysis and application o	e, as I met f " qu	one of humanistic outcomes. Dev hods for questionnaire estimate. uality adjusted life years"	elopment of critical app Development of critical a	raisal for appraisal
Course contents:					
Lectures					
Concept of health state and hea surveys. Basic psychometric ca Application of tools in cost-utili	alth related quality of life. E racteristics of questionnair ty anlysis. The value of asse	Basic e (va essmo	principles for creating the questic ilidity, reliability, sensitivity). Pre- ent of quality of life and ethical as	onnaire for assassment. <i>I</i> frencies and theire meas spects in survey.	Available surment.
Practical classes					
Content analysis and categori interpretation of the general c cost-utility analysis.	zation of survey. Domein aracteristics of survey. Calo	ana culati	lysis correlated with health stat on of QALY. Interpretation of res	tus of patients. Calculat sults. Results from the p	tion and oublished
Recommended literature:					
1. Fayers PM, Machin D. Quality Chichester: John Wiley & Sons;	y of life: Assessment, Analy 2007.	sis ar	nd Interpretation of patient report	ted outcomes. 2nd Ed.	
2. Streiner DL, Norman GR. Hea Oxford University Press; 2008.	lth Measurement Scales: A	Prac	tical Guide to Their Development	and Use. 4th Ed. New Yo	ork:
3. Drummond MF, O'Brien B, St ed. New York: Oxford Universit	oddart GL, Torrance GW. M y Press; 2005.	letho	ods for the Economic Evaluation o	f Health Care Programm	es. 3rd
	The total o	f act	ive learning classes		
Lectures: 15 Practical classes: 15					
Research work: 15			Other forms of teaching: 15		
Teaching methods:					
Methods for delivering the curr	icula include: lectures, inte	racti	ve activities, case analysis, tests, c	on-line teaching.	
Grading system					
Exam prerequisites	Points	Final exam Points		Points	
Active participation in lectures	20	Practical			
Practical classes	20	Written		60	
Workshops		Oral			
Colloquia					
Seminars					
Other activities		1			
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University of Belgrade
Faculty of Pharmacy



University of Belgrade Faculty of Pharmacy	PHARMACOECONO	PHARMACOECONOMIC AND PHARMACEUTICAL LEGISLATION				
Study programme: Pharmad	coeconomic and Pharmaceutic	al Le	gislation			
Course title: Health technol	ogy assessment					
Teachers: Lakic M. Dragana,	, Bogavac-Stanojevic B. Natasa					
Course status: elective						
Semester: II	Year of studies:					
ECTS points: 4	TS points: 4		Course code: SFFLI3			
Requirements: none						
Course aims:						
Understanding the process	of health technology assessme	nt. U	nderstanding the importance of	health technology ass	sessment	
Course outcomes:						
Understanding the process assessment.	s of health technology asses	smer	nt. Development of critical ap	praisal in the health	technology	
Course contents:						
Lectures						
Health technology and heat technology assessment. Use	alth technology assessment ( e of other sources for HTA. The	HTA) proc	. EU model of HTA.The conte ess of decision making based or	nt of evaluation. Sten best available eviden	ps in health ce.	
Practical classes						
Assessment of the HTA cont	ent. Results of the HTA and its	appl	ication. Critical analysis of selec	ted HTA.		
Recommended literature:						
1. National and international	al laws and regulations		I shaws showing in the solution of the solution is a show		haalth	
policy decision making: com Sweden. Int J Technol Asses	parison of health technology a s Health Care 2009.	isses	sment agencies in Germany, Uni	ited Kingdom, France,	and	
3. Hailey D et al. HTA agenci	es and decision makers. INAHT	FA 20	10.			
	The total o	f act	ve learning classes			
Lectures: 15			Practical classes: 15			
Research work: 15     Other forms of teaching: 15						
Teaching methods:						
Methods for delivering the o	curricula include: lectures, inte	racti	ve activities, case analysis, tests,	, workshop, on-line tea	aching.	
	G	radiı	ng system			
Exam prerequisites	Points	Final exam		Points		
Active participation in lectur	res 20	Practical				
Practical classes	20	Written 60				
Workshops		Oral				
Colloquia						
Seminars						
Other activities						

PHARMACOECONOMIC AND PHARMACEUTICAL LEGISLATION



## Study programme: Pharmacoeconomic and Pharmaceutical Legislation Course title: Marketing authorization files and postmarketing surveilance of mediicnes

# Teachers: Lakic M. Dragana Course status: elective Semester: II Year of studies: I ECTS points: 4 Course code: SFFLI2 Requirements: none FELI2

#### **Course aims:**

Understanding national, european and international regulations for obtaining the marketing authorization. Understanding the content of the file. ADR and pharmacovigilance

#### **Course outcomes:**

Knowledge and understanding regulations for the marketing authorization. Understanding the content of file. Acquiring knowledge connected with ADR.

#### **Course contents:**

Lectures

Regulations that define marketing authorization. The content of the file according to the CTD. The content of the file according to the EU format. Obtaining the marketing authorization in Serbia and EU - centralised, decentralised, national and mutual recognition procedure. Documenation needed for the marketing authorization. Types of marketing authorization. Postmarketing surveilance of medicines - importance, obligations from the regulatory part and MAH

Practical classes

Content of registracion file. Differencies from old and new format. PSUR. Analysis of information regarding the safety of medicine in the PIL

#### **Recommended literature:**

1. National and international laws and regulations

2. Strom BL. Pharmacoepidemiology. 4th Ed. Chichester: John Wiley & Sons; 2005

3. Vlajinac H, Jarebinski M (eds) Epidemiologija. Belgrade: School of Medicine; 2009

4. Hartzema AG , Porta M, Tilson HH (editors). Pharmacoepidemiology. An Introduction. 3th Ed. Cincinnati: Harvey Whitney Books Company; 1998

The total of active learning classes			
Lectures: 15	Practical classes: 15		
Research work: 15	Other forms of teaching: 15		
Tooching methods			

#### Teaching methods:

Methods for delivering the curricula include: lectures, interactive activities, case analysis, tests, workshop

Grading system				
Exam prerequisites	Points	Final exam	Points	
Active participation in lectures	20	Practical		
Practical classes	20	Written	60	
Workshops		Oral		
Colloquia				
Seminars				
Other activities				

University of Belgrade Faculty of Pharmacy

Seminars

Other activities

#### Specialized academic study

PHARMACOECONOMIC AND PHARMACEUTICAL LEGISLATION



Study programme: Pharmacoeconomic and Pharmaceutical Legislation					
Course title: Drug supply					
Teachers: Petrova I. Guenka, Lakic M.	Teachers: Petrova I. Guenka, Lakic M. Dragana				
Course status: core					
Semester:   Year of studies:					
ECTS points: 7	CTS points: 7 Course code: SFFLO3				
Requirements: none	Requirements: none				
Course aims:					
Understanding the main parts of drug supply; importance of the methods for calculating drug needed					
Course outcomes:					
Understanding the process of drug supply. Training for the responsibilities in drug and medical devices supply . Application of the consumption methods					
Course contents:					
Lectures					
Main parts of drug supply. Selection of the drug - criteria, concept of essential medicines. Methods for quantifying the needs in mediicne (consumption method, morbidity method). Procurment of medicines - principles and practice, methods. Distribution of medicines - principles and requirments. Stock control - calculating the stock. Use of medicines - factors that affect use of medicines. Evaluation of drug use.					
Practical classes					
The curricula follows the topics covered in the theoretical part. Creating the criteria for selection of essential medicines (e.g. antibiotics). Exemples of drug formulary - differencies. Calculating the consumption of certain class of drugs using the consumption and/or morbidity method. Preparation of the procurement documentation. Procurement contract. ABC analysis - application in stock control. Monetary and natural units for drug consumption - examples and discussion. DDD system and its application in drug use					
Recommended literature:					
1. World Health Organization. Managing Drug Supply. 2nd ed. Connecticut: Kumarian Press: 1997					
2. Lilja J, Salek S, Alvarez A, Hamilto D. Pharmaceutical system. Chichester: John Wiley & Sons. 2008					
3. Current laws and regulation in Serbia					
The total of active learning classes					
Lectures: 15			Practical classes: 30		
Research work: 15			Other forms of teaching: 30		
Teaching methods:					
Methods for delivering the curricula include: lectures, interactive activities, case analysis, panel discussion, workshop, tests, on- line teaching.					
Grading system					
Exam prerequisites	Points	Final exam Points		Points	
Active participation in lectures	20	Practical			
Practical classes	30	Written 50		50	
Workshops		Oral			
Colloquia					

University of Belgrade Faculty of Pharmacy

#### Specialized academic study

PHARMACOECONOMIC AND PHARMACEUTICAL LEGISLATION

