



MINISTERSTVO ŠKOLSTVÍ,
MLÁDEŽE A TĚLOVÝCHOVY



OP Vzdělávání
pro konkurenceschopnost

INVESTICE DO ROZVOJE VZDĚLÁVÁNÍ

PHYTOPHARMACEUTICALS

academic year 2018/19

**LECTURE I – Introduction – definition,
legislative status, basic terms.**

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PHYTOPHARMACEUTICALS

- ▶ The aim of the course is to provide the basic knowledge about phytopharmaceuticals and discuss the position of phytotherapy in the self-treatment. The course deals with the most commonly used groups of phytopharmaceuticals according to their pharmacological effect, provides the information about the most frequently used drugs in each group. Discuss the role of a pharmacist in phytotherapy.
- ▶ optional course, 2 credits
- ▶ time requirements: lectures – 1/0/0 a week (= 2 hours lecture/week in first 7 weeks of summer semester)
- ▶ recommended year of study – 3rd
- ▶ guarantor/lecturer
 - ▶ Dr. Ivana Daňková
 - ▶ dankovai@vfu.cz, office No 247
- ▶ the course will be available on Moodle - presentations of lectures (pdf)

What is necessary to know for studying PHYTOPHARMACEUTICALS?

- ▶ good knowledge of:
 - ▶ Botany – plant systematics, Latin names of plants and plant families, plant morphology
 - ▶ Pharmacognosy – basic terminology, chemical constituents of plants (secondary metabolites) – their properties, effects..., which plant part is used
- ▶ basic knowledge of:
 - ▶ Human Physiology, Pathology
 - ▶ Pharmacology
 - ▶ Pharmaceutical technology

PHYTOPHARMACEUTICALS

- ▶ „Medicines that are exclusively or predominantly composed of plants, plant parts, chemical constituents of plants.“
- ▶ „herbal drug“ = a plant or a plant part that is used for the treatment or prevention of diseases or for influencing of physiological state



PHYTOTHERAPY

- ▶ known also as a **herbalism**
- ▶ the use of plants and plant products for medicinal purposes. Herbal medicine usually refers to plants that are not part of the normal diet.
- ▶ part of **traditional medicine**, nowadays regarded as alternative therapy
- ▶ Herbal medicines for therapeutic purposes have been explicitly used since the dawn of human civilization to maintain health and to treat diseases. WHO estimates that about **three-quarters of the world's population** currently uses herbs and other forms of traditional medicines.



PHYTOPHARMACEUTICALS

- ▶ complicated legislative status – the most of phytopharmaceuticals are not included into official medical care
- ▶ according to the WHO:
„Phytopharmaceuticals **don't belong** to the essential medicine.“



PHYTOPHARMACEUTICALS

- ▶ 1) some of them are approved as medicines by the state medicines authority (in the Czech Republic: **SÚKL** = State Institute for Drug Control)
- ▶ exactly defined composition (standardised, quantified extracts), proven efficiency, safety...
- ▶ the preparations have „SÚKL code“
- ▶ these phytopharmaceuticals can be sold only in a pharmacy !



[Medicinal products database](#)[Pharmacies database](#)[Clinical trials database](#)[Important Information](#)[Reports to SUKL](#)[Supplies of medicinal products](#)[Reviews and lists](#)[Home](#) / Medicinal products database

Search

Beginning of medicinal product name: SÚKL code (without zero at the beginning): **ATC group:**Beginning of active substance name:

Route of administration:

MA status:

- All medicinal products
- Prescription-Only medicinal products
- Medicinal products with blue strip
- Restricted Prescription-Only medicinal products
- OTC medicinal products
- OTC with restricted dispensing
- Medicinal products used within specific therapeutic programmes
- Selected medicinal products
- Homeopathics
- Foods for special medical purposes
- Medicinal product within the scope of parallel import
- Medicinal product with foreign language batch
- Medicinal product under suspicion of doping


Registration number: **Brailles:**

- Approved – name of the medicinal product in Braille on the packaging was confirmed.
- Exemption



ATC Groups

- ▶ Anatomical Therapeutic Chemical Classification System – defined by the WHO, see www.whooc.no.
- ▶ A: Alimentary tract and metabolism
- ▶ B: Blood and blood forming organs
- ▶ C: Cardiovascular system
- ▶ D: Dermatologicals
- ▶ G: Genito-urinary system and sex hormones
- ▶ H: Systemic hormonal preparations, excl. sex hormones and insulins
- ▶ J: Antiinfectives for systemic use
- ▶ L: Antineoplastic and immunomodulating agents
- ▶ M: Musculo-skeletal system
- ▶ N: Nervous system
- ▶ P: Antiparasitic products, insecticides and repellents
- ▶ Q: Veterinary products
- ▶ R: Respiratory system
- ▶ S: Sensory organs
- ▶ V: Various preparations → V11 = Phytopharmaceuticals and animal products

-  Medicinal products database
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Beginning of medicinal product name:

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- All medicinal products
- Prescription-Only medicinal products
- Medicinal products with blue strip
- Restricted Prescription-Only medicinal products
- OTC medicinal products
- OTC with restricted dispensing
- Covered by health insurance [?]
- Fully covered by health insurance [?]
- Marketed [?]
- Not Covered by health insurance [?]

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List of records on page

Number of records: 213

Name of the medicinal product		Supplement	
SÚKL code	Registration Number	SPC [?]	PIL [?] ATC group MA status [?]
 ALVISAN NEO			POR SPC 20X1.5GM-SÁ III
0187223	94/ 615/69-C	alvisanneo.pdf	alvisanneo.pdf V11 R
 ALVISAN NEO			POR SPC 20X1.5GM-SÁ II
0187222	94/ 615/69-C	alvisanneo.pdf	alvisanneo.pdf V11 R
  ALVISAN NEO			POR SPC 1X100GM
0004364	94/ 615/69-C	alvisanneo.pdf	alvisanneo.pdf V11 R
  ALVISAN NEO			POR SPC 20X1.5GM-SÁ I
0043954	94/ 615/69-C	alvisanneo.pdf	alvisanneo.pdf V11 R
 ALVISAN NEO			POR SPC 25X1.5GM-SÁ
0043955	94/ 615/69-C	alvisanneo.pdf	alvisanneo.pdf V11 R
 AMOL			POR GTT SOL 1X5ML



PHYTOPHARMACEUTICALS

- ▶ 2) some phytopharmaceuticals are included into group „**food supplements**“ (= „dietary supplements“)
- ▶ using of these products is controlled by state institutions that are covered by the Ministry of Agriculture (SZPI = CAFIA, Czech Agriculture and Food Inspection Authority) and the Ministry of Health (Health Officer of the CR)
- ▶ these products can be sold in a pharmacy or in herb shops and natural food stores



Finding informations:

[Advanced search »](#)

- About CAFIA
- Press Releases
- Reports
- Official Board
- Public Procurement
- Jobs
- Act No. 106/1999 Coll.
- INFORMATION S**
- Import
- Export
- Wine
- Entrepreneurs
- Legislation
- Download
- Consumers
- CONTACTS**
- Organizational Structure
- Mail to Us
- Contacts for the Public
- Contacts for Media
- Links



Welcome

CAFIA is a state administration body subordinate to the Ministry of Agriculture. It is a state authority responsible for supervision of safety, quality and labelling of foodstuffs. [More »](#)

- News** [More »](#)
- 01/26/2018** CAFIA detected sale of food supplements containing unauthorised substance for erection enhancement
 - 01/22/2018** CAFIA checked foodstuffs treated by ionising radiation
 - 01/18/2018** Inspections confirmed high quality of foodstuffs with KLASA and Regional Foodstuff awards
 - 01/11/2018** Almost a half of assessed ice added to drinks in restaurants failed to comply with health and hygiene limits
 - 01/05/2018** CAFIA detected pesticide chloropyrifos in another lot of apples from Poland
 - 12/13/2017** CAFIA revealed barrel wine adulterated with unauthorised synthetic aromatic substances
 - 12/12/2017** CAFIA states that conditions of frying oils and fats in restaurants are unsatisfactory
 - 12/08/2017** CAFIA releases results of long-term inspection focused on fruit and vegetables

Competencies of CAFIAs´ regional inspectorates



 Wine
 

Částečně zkvašený hroznový mošt - červený
 Miroslav Andráš
 Víno bylo falšováno

Inquiry [»](#)

Can you recognise, as a consumer, that the restaurant staff prepared the meal on burnt oil?

a) Yes (1)

b) No (2)

Votes: 3

[Inquiries results](#)

News on web [»](#)

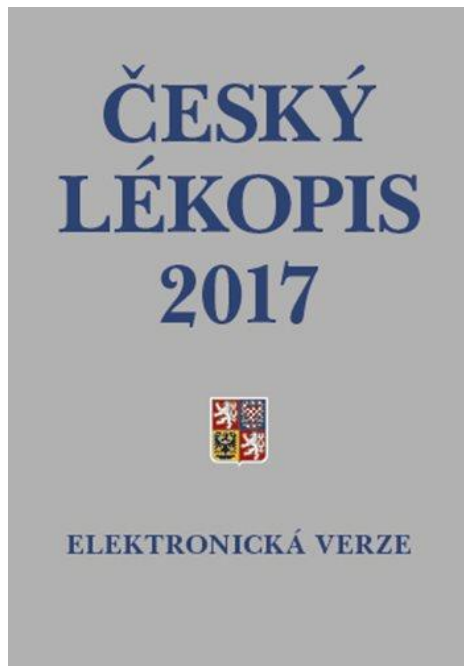
CAFIA Annual Report 2016

Announcement of retail business operator offering tobacco products

- Most read** [»](#)
- CAFIA Control Activities
 - CAFIA Laboratory Activities
 - Consumers
 - Entrepreneurs
 - Information for Importers

PLANT DRUGS IN PHARMACOPOEIAS

- ▶ ČESKÝ LÉKOPIS 2017
(PHARMACOPOEIA
BOHEMICA MMXVII, Ph.B.
MMXVII)



- ▶ EUROPEAN
PHARMACOPOEIA
9th Edition (2016)
PhEur 9th Edition 2016 (9.0)
- ▶ <http://www.edqm.eu/en/european-pharmacopoeia-9th-edition>



European Pharmacopoeia

9th Edition

Publication schedule and general information

The 9th Edition (including Supplement 9.5) is comprised of 2376 monographs (including dosage forms), 361 general texts (including general monographs and methods of analysis) and about 2690 reagents.

Commission Sessions		Edition/ Supplement	Publication schedule	Corrections to be taken into account as soon as possible and not later than	Implementation date
Session No.	Date				
153	November 2015	9th Edition*	July 2016	31 August 2016	1 January 2017
154	March 2016	9.1	October 2016	30 November 2016	1 April 2017
155	June 2016	9.2	January 2017	28 February 2017	1 July 2017
156	November 2016	9.3	July 2017	31 August 2017	1 January 2018
157	March 2017	9.4*	October 2017	30 November 2017	1 April 2018
158	June 2017	9.5	January 2018	28 February 2018	1 July 2018
159	November 2017	9.6	July 2018	31 August 2018	1 January 2019
160	March 2018	9.7*	October 2018	30 November 2018	1 April 2019
161	June 2018	9.8	January 2019	28 February 2019	1 July 2019
162	November 2018	10th Edition*	July 2019	31 August 2019	1 January 2020

HERBAL PHARMACOPOEIAS

e.g.

- ▶ Deutsches Arzneibuch (German Pharmacopoeia)
 - ▶ British Herbal Pharmacopoeia
 - ▶ American Herbal Pharmacopoeia and Therapeutic Compendium
 - ▶ U.S. Food and Drug Administration (FDA)
 - ▶ Indian Herbal Pharmacopoeia, Ayurvedic Pharmacopoeia of India
 - ▶ Japanese Herbal Medicine Codex,
 - ▶ etc.
-
- ▶ European Scientific Cooperative on Phytotherapy (ESCOP)
 - ▶ British Herbal Medicine Association (BHMA)

PHYTOTHERAPY – Risks

▶ „*The natural products are always healthy and harmless.*“

– is it true?

- ▶ self-medication - difficult determination of exact diagnosis
- ▶ wide range of therapeutic use
- ▶ the active constituents of herbal drugs are not well established
- ▶ mixture of many constituents, unknown exact composition
- ▶ not exact dosage
- ▶ presence of toxic compounds, allergens, unwanted components – e.g. pesticides, heavy metals



PHYTOTHERAPY – Risks

- ▶ chemical composition variability
 - ▶ natural variation/biodiversity
 - ▶ influence of harvest, drying, storage...
- ▶ microbial contamination
- ▶ standardization, stability and quality control testing are relatively time consuming, tedious and highly priced
- ▶ selective analytical methods may not exist
- ▶ reference compounds may not be available commercially

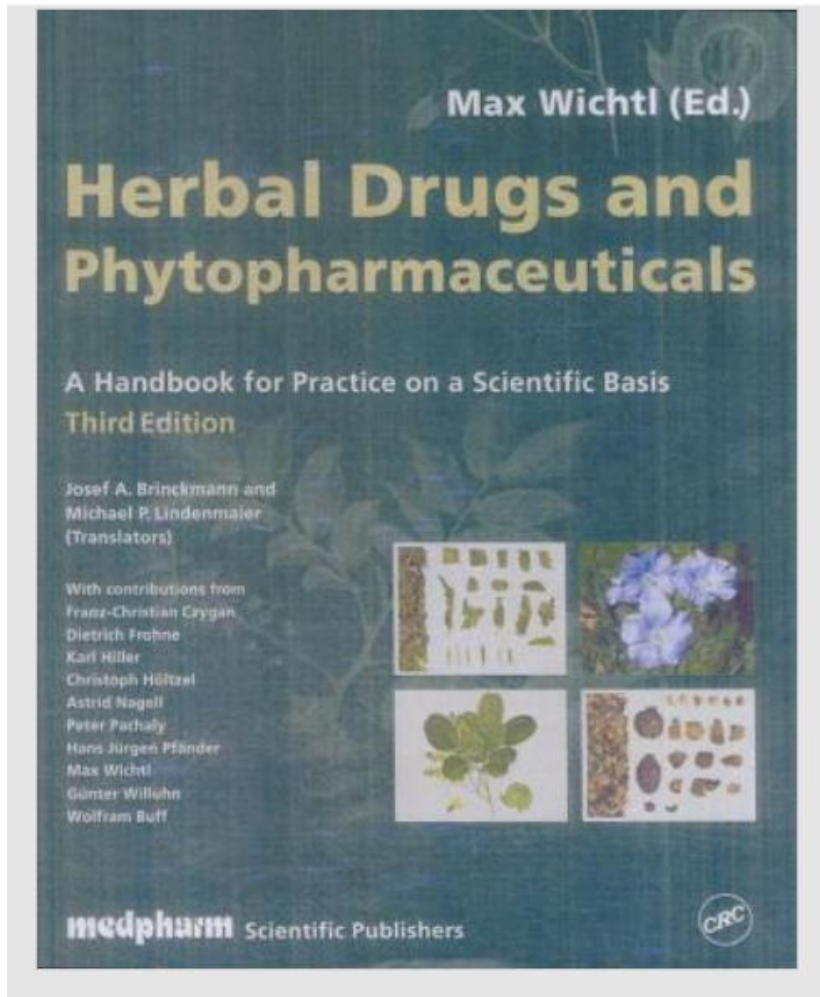


General information for using phytomedicines

- ▶ Do not use longer than a few days/weeks without consulting your physician
- ▶ If the symptoms do not improve, or even deteriorate, or if undesirable effects or an unusual reaction occur, consult your doctor.
- ▶ In the event of overdose or accidental usage by a child, consult your doctor.
- ▶ Caution in pregnancy, nursing, for children (see the recommendation of producer)
- ▶ Contraindication in case of hypersensitivity to any constituent!



Recommended literature



Herbal teas – important producers on Czech market

- ▶ LEROS <http://leros.cz/>
- ▶ MEGAFYT Pharma <http://www.megafyt-pharma.cz/>
- ▶ APOTHEKE <http://www.apotheke.cz/>
- ▶ Dr. POPOV <http://www.drpopov.cz/>
- ▶ GREŠÍK Valdemar <http://www.gresik.cz/>
- ▶ Pavel Váňa <http://www.ipavelvana.eu/>
- ▶ TEEKANNE, HIPPI, HERBEX, FYTOPHARMA, etc.



Tea for health and safety of the whole family

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TEAS BY KIND



Single-herb teas

A range of single-herb herbal teas as loose tea and in individual tea bags. High-quality pure herbal teas without chemical additives and aromas.



Herbal mixtures

Medicinal tea mixtures for the prevention and treatment of diseases of all basic medical indications. High-quality pure herbal teas without chemical additives and aromas. Sold in individual tea bags and as loose tea.



Teas for children

A line for mothers and their babies. Herbal and herbal and fruit mixtures as well as fruit teas made of natural ingredients, free of chemicals and preservatives. They are not sweetened with sugar or any other sweeteners.

Phytomedicines – important producers on Czech market

- ▶ ZENTIVA, IVAX/TEVA – pharmaceutical companies
- ▶ WALMARK <https://www.walmarkgroup.com/en/brands>
- ▶ Dr. MÜLLER <http://www.muller-pharma.cz/>
- ▶ AROMATICA <http://www.aromatica.cz/>
- ▶ GREŠÍK <http://www.gresik.cz/>
- ▶ TEREZIA Company <https://www.terezia.eu/en>
- ▶ MedPharma <http://www.medpharma.info/>
- ▶ PharmaSuisse Laboratories, Angelini Pharma, Jamieson, GS, Naturevia (Swiss)...
- ▶ Dr. THEISS, KNEIPP, HerbalMed Dr. WEISS, etc.



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URINAL



BELIEMA



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MULTIVITAMINS

SPEKTRUM



GUT HEALTH

BIOPRON



COLD & COUGH

SINULAN



SEPTOFORT



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