

CONTEMPORARY ETHICAL
AND MORAL DILLEMAS IN
COMMUNITY PHARMACY'S
PRACTICE

HOLISTIC COMMUNITY PHARMACY
INTERNATIONAL CONFERENCE 2020

Poster Session

19 November 2020

CONTEMPORARY ETHICAL AND MORAL DILLEMAS IN COMMUNITY
PHARMACY'S PRACTICE
HOLISTIC COMMUNITY PHARMACY INTERNATIONAL CONFERENCE 2020
Poster Session

Authors: Azra Uzunović, Marko Andrić, Irma Hermina Klemenc, Nina Strah, Matija Centrih, Ana Deželak

Editor: Martina Puc

Technical editor: Špela Vozelj

Published by: COVIRIAS, Parmova 14, SI-1000 Ljubljana

Phone: +38612322097, info@covirias.eu

Ljubljana, November 2020

1st edition

Free publication

The publication is published in e-format (.pdf).

The publication is published publicly on website <https://covirias.eu>

Kataložni zapis o publikaciji (CIP) pripravili v Narodni in univerzitetni
knjižnici v Ljubljani

[COBISS.SI-ID=36766211](#)

ISBN 978-961-95129-1-3 (pdf)

TABLE OF CONTENTS

SHOULD COMMUNITY PHARMACY UPHOLD DISPENSING MEDICINES PRESCRIBED BY RETIRED PRACTITIONER WORKING ILLEGALLY?	2
PROFIT VERSUS LEGISLATION, MORAL AND PROFESSIONAL PRINCIPLES IN COMMUNITY PHARMACIES?	6
IS THE DIFFERENCE BETWEEN NUTRITION UNDER THE LABEL OF PRESCRIBED MEDICATION AND THE ONE COMING FROM FOOD SUPPLEMENTS ONLY BUREAUCRATICAL OR BIOLOGICAL TOO?.....	10
THE ETHICS IN SELF- MEDICATION OF CHRONIC HEART FAILURE	15
DISPENSING CRATAEGUS TEA PRODUCTS FOR SELF-MEDICATION.....	19

FOREWORD

An occurrence of ethical and moral dilemmas in any field of healthcare shouldn't be a surprise. Professionals have enormous knowledge and means compared to a layman and at the same time enough opportunities to misuse them for their own personal advantage with a threat of people's health and even their lives. Awareness of their position is a first step to a trustful relationship.

Community Pharmacies are financed based on the amount of products they pass to people and not based on quality of their work. That is a fact influencing the content of their everyday work. The existence of codes is therefore supporting the border line between Community Pharmacies and plain retail shops. However, any code in writing is not enough. The practice is what matters.

COVIRIAS academia actively supports building the identity and awareness of Community Pharmacies based on ethical and moral principles. One of the activities is a regular inclusion of a poster session on ethical and moral dilemmas in practice of Community Pharmacies within Holistic Community Pharmacy[®] yearly conferences. Community Pharmacists are invited to present their ethical and moral dilemmas they come across in their daily practice.

The following cases are the official posters of the Holistic Community Pharmacy[®] 2020 conference on Self-medication and Self-treatment. They should raise open questions and dilemmas, enabling an improvement in a Community Pharmacy practice. Presented dilemmas are coming from different countries. How close are we in the state of the art in the community pharmacy profession? What are the systemic solutions? It is evident the regulation is struggling to follow the development in everyday life. It is true even for such a highly regulated field as medicinal products. With the advance in knowledge of nutrition, oral medicinal products with nutrients are coming under the scrutiny of facts. What is the rational to maintain nutrients among registered medicines? Pharmacological effect? And the complex question is rising also from the last two dilemmas. They are illustrating the time and the place when and where you should and can address the decision, which products are you placing on your shelves. Is defining professional criteria for the selection of products an ethical and moral dilemma or a minimal professional standard?

Authors are young pharmacists openly inviting colleagues to help them address their dilemmas. The responsibility is now on the national professional chambers to discuss these dilemmas and present their official standpoint on every case presented and the following actions to improve the practice. Every passive professional chamber will demonstrate their true faith in the future of Community Pharmacies.

Editor

mag. sci. Martina Puc, MPharm, spec., MBA

SHOULD COMMUNITY PHARMACY UPHOLD DISPENSING MEDICINES PRESCRIBED BY RETIRED PRACTITIONER WORKING ILLEGALLY?

AZRA UZUNOVIĆ

JU „Internacionalna ljekarna/apoteka“ Vitez

THE SITUATION IN QUESTION

In January 2020 a pharmacist received a piece of paper that can't be considered as a prescription according to the Ordinance on the manner of prescribing and dispensing medicines in FB&H [1]. It was written and verified by the local well-known retired physician still obtaining practice. Physician prescribed ranitidine tablets to an 8-year-old child describing child's condition. As on September 13th EMA announced a review ranitidine medicines following detection of N-nitrosodimethylamine [2] all ranitidine forms were withdrawn from the market in Bosnia and Herzegovina by the end of September. The pharmacist guided with that known fact asked additional questions about the child's condition to make a correct assessment to the therapy and explained to a child's mother that ranitidine was not available for use anymore and recommended in the domain of his responsibility and knowledge a ginger dietary supplement to calm the caused nausea. As „mind-body interventions (hypnosis, biofeedback), botanicals and supplements (ginger, enteric-coated peppermint oil), aromatherapy, and acupuncture have emerging evidence for effectively treating pediatric nausea“ [3] the pharmacist explained the usage of appropriate ginger dietary supplement suitable for children to a mother. A few days later, the retired physician came to the pharmacy complaining about the non-cooperation of the dispensing pharmacist with the physician pointing out the pharmacist should have called the physician in order to inform about the ranitidine withdrawal and further consultation regarding the therapy for related child.

REGULATION

According to the Law on medicine of FB&H, Article 20, the physician independently performs the tasks of his profession only within the scope of his professional title determined by a license issued by the competent chamber. [4]

If the physician is the holder of a regular license when acquiring the status of a retired it is revoked within the day of acquiring the rights from retirement insurance, and to the physician, the physician's chamber may issue a temporary license. [5]

For example, according to the Medical Board of California physician with a retired license cannot write prescriptions or practice medicine, or a physician not authorized to engage in the practice of medicine may not own a business that is engaged in the practice of medicine, and also the holder of a retired license is prohibited from conducting a professional practice, which would preclude him or her from being a partner in a professional practice.[6]

OBSERVED PRACTICE

The pharmacist made action in order with the current situation and used his own right and obligation to help, as a healthcare worker guided by his knowledge and professional expertise without any mentioning the physician in order to disrespect him. Acting in accordance with the law and avoiding harm to the patient's health due to lack of information of a physician who is still working illegally in retirement, the pharmacist took over responsibility to help the child with nausea in the way of his domain guided only by principles of his profession and human willingness to help.

THE DILEMMA

Our community pharmacy continuously encounters the dilemma about dispensing medicines prescribed by this retired physician. First dilemma related to this case is whether is justified to obtain this dispensing operations since the form of the prescriptions is not aligned with the referring legislation and risking the money fine defined by the Article 68 of Law on Pharmaceutical Activity of Federation of Bosnia and Herzegovina? [7] The dispensing pharmacist did not show disrespect towards the physician by refusing to dispense the ranitidine by his own wish and choice. On the contrary, it was the lack of the physician's information since the physician is retired and was obviously not informed about the ranitidine therapeutic usage withdrawal. Or was the pharmacist obliged to make a contact to the physician who already endangered our community pharmacy with the huge moral and ethical dilemma? The physician's action of visiting the pharmacy and the complaint he made speaks for itself and a lot about the pharmacists' role in the whole healthcare system.

CONSEQUENCES

By continuous dispensing medicines not accompanied with a proper medicinal documentation (as in this case) the community pharmacy risks a money fine in accordance to the related law. [7]Unfortunate consequence for the physician was possible patient's distrust caused by lack of information since the physician worked illegally and

was not updated with the events in the profession. The pharmacist indirectly and unintentionally harmed the physician's reputation, and the physician reacted with the visit and complaint. But was this justified considering the whole situation? Is it possible, and by the physician demanded, to contact the physician for consultations justified knowing of the physician's illegal actions?

CONTINUATION OR ESTABLISHMENT OF NEW PRACTICES

By accepting dilemma alike situations as normal, especially in the healthcare sector, we run the risk of behaving in a way that deviates from moral and ethical codes as normal.

In case of incorrect prescription, the pharmacist is obliged to the doctor toward of the established irregularity, but in such a way that it does not cause doubt in the correctness of the physician's work in the person to whom the medicine is prescribed. If the pharmacist cannot contact a physician, in case the prescription is not clear he is obliged to return the prescription in a suitable manner with the necessary explanation. [8] So, it is moral and ethical obligation for pharmacist to behave in relation to the valid legislation in the pharmacy profession. Continuation of deviant form of behavior in this area leads community pharmacies to the edge cliff towards common retail stores and pharmacy professionals towards integrity loss.

POSSIBLE PROPOSALS FOR AMENDMENTS

Ethical principles are used in health care to provide a moral grounding for the day to day work of providers. The study of ethics remains an important part of education and culture for nearly all care providers charged with supporting the health of individuals in society. [9,10]The literature suggests that pharmacists may need additional guidance for ethical decision-making in practice [11] and that there have been calls for integration of novel ethical schemas for grappling with complex and especially commercial aspects of health care [12]. The described case showed us that constant collaboration and communication between pharmacists and physicians is necessary within the limits of compliance with the law and code of moral and ethics. The necessary guides will arise only from the examples we notice in everyday practice and discuss about them. The occurrence of such a case in practice indicates possible and necessary amendments to the state Law on medicine and the Code of ethics and morals, if the presence of illegal unreported practice of a retired physician continues.

REFERENCES:

1. Ordinance on the manner of prescribing and dispensing medicines in FB&H, Official Gazette of the Federation BiH No. 29/08 available at http://www.podaci.net/_gBiH/propis/Pravilnik_o_nacinu/P-npilij04v0829.html (accessed 22.08.2020)

2. Available at <https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma> (accessed 25.08.2020)
3. Arruda, J. Ming Yeh, A. Integrative Approach to Pediatric Nausea, *Pediatric Annals*. 2019;48(6):e236-e242
4. Law On Medicine in FB&H, Official Gazette of the Federation BiH No. 56/13 available at <https://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-lijecnistvu> (accessed 24.08.2020)
5. PRAVILNIKO UTVRĐIVANJU ZAJEDNIČKIH KRITERIJA ZA LICENCIRANJE ČLANOVA LJEKARSKE/LIJEČNIČKE KOMORE FBiH I ČLANOVA KANTONALNIH/ŽUPANIJSKIH LJEKARSKIH/LIJEČNIČKIH KOMORA, available at <https://ljkzedo.ba/wordpress/wp-content/uploads/2017/12/PRAVILNIK-LICENCA-21.04.18..pdf> (accessed 25.08.2020.)
6. Available at https://www.mbc.ca.gov/Licensees/Retired_Status_FAQ.aspx#4 (accessed 26.08.2020)
7. Law on Pharmaceutical Activity of Federation of Bosnia and Herzegovina, Official Gazette of the Federation BiH No. 40/10, Articles 37, 39 and 68, available at <http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-apotekarskoj-djelatnosti> (accessed 25.08.2020)
8. Edina Stević et al. Dobra praksa propisivanja i izdavanja lijekova, Ministarstvo zdravstva Kantona Sarajevo, Institut za naučnoistraživački rad I razvoj KCUS, Sarajevo 2011. available at <http://judzks.ba/wp-content/uploads/2018/09/Dobra-praksa-propisivanja-i-izdavanja-lijekova.pdf>(accessed 27.08.2020)
9. Dahnke M.D. Utilizing codes of ethics in health professions education. *Adv. Health Sci. Educ.* 2014;19:611–623.
10. Buerki R.A., Vottero L.D. *Pharmacy Ethics: A Foundation for Professional Practice*. American Pharmacists Association; Washington, DC, USA: 2013.
11. Cooper R.J., Bissell P., Wingfield J. Ethical decision- making, passivity and pharmacy. *J. Med. Ethics.* 2008;34:441–445.
12. Wingfield J., Bissell P., Anderson C. The Scope of pharmacy ethics—An evaluation of the international research literature, 1990–2002. *Soc. Sci. Med.* 2004;58:2383–2396.

PROFIT VERSUS LEGISLATION, MORAL AND PROFESSIONAL PRINCIPLES IN COMMUNITY PHARMACIES?

AZRA UZUNOVIĆ, MARKO ANDRIĆ
JU „Internacionalna ljekarna/apoteka“ Vitez

THE SITUATION IN QUESTION

The pharmacist receives a phone call from a female friend asking him for advice for a treatment of *herpes labialis*. Pharmacist gives her advice to go to the nearest pharmacy and buy OTC aciclovir ointment, oral propolis solution and B complex tablets. He also explained to her how to use all he recommended. The girl went first to the cosmetics market and bought there available oral propolis solution and lipstick for herpes treatment. Afterwards she visited the nearest pharmacy and the pharmacist there sold her coldly aciclovir 200 mg tablets without any given explanation how to use it. As she was confused, she called her friend pharmacist to ask him what to do. The friend pharmacist asked her to send him photos of the medicine she got in the pharmacy and the photos confirmed her story. He told her that is not necessary to take those tablets, and that the lipstick and oral propolis solution will help her and advised her to continue using them instead of tablets.

REGULATION

Aciclovir 200 mg tablets according to the Official Drug Registry in B&H [1] are Rx and the dispensing pharmacist obviously disobeyed the Law on Pharmaceutical Activity of Federation of Bosnia and Herzegovina[2] by dispensing and recommending Rx medicine without the prescription. Also, GPP consists of several general and special principles. The first of the general principles and guidelines relates to information: pharmacists in the pharmacy should give advice and information on how to use the drug in a safe and effective way with maximum therapeutic outcome. The third general principle applies to pharmacists and support staff and states that: compliance with the code of ethics is mandatory and all employees in the pharmacy must maintain the level of knowledge and competence to be able to provide the service in the best way. [3]

OBSERVED PRACTICE

The friend pharmacist gave advice to his friend guided by legislative and moral principles of the profession and instructing her to visit nearest pharmacy with the counting trust that she will get appropriate and professional service at any pharmacy she visits. The girl went first to the cosmetic market and then to a pharmacy. Unfortunately, she got the same kind of service in this pharmacy as in the cosmetic market looking out of her perspective. What should be to the visitor a well-known difference between a community pharmacy and a common retail or cosmetics store? Buying objects in this case have the same meaning although it is not so according to pharmacy profession principles.

THE DILEMMA

Arising number of similar moral and ethical dilemma is a warning. The friend pharmacist in order to respect other colleague's expertise and not to endanger reputation of the profession is actually acting protective over the possible harmful and illegal colleague's actions. One of the existing and valid code of deontology appoints pharmacists to protect the interest and reputation of the pharmacy or other health institution, within the limits of his professional qualification and competence, to prevent wrong illness treatment and may, in the interest of the patient, refuse to dispense the medicine. [4] The pharmacist acted protectively even to the patient advising her not to use the aciklovir tablets.

CONSEQUENCES

Legal consequences for the dispensing Rx medicine without a prescription or valid medicinal documentation and indication are defined, besides the basic professional principles, by the state law [2] defining the amount of money fine for the law offender. Aciclovir dose of 200 mg would probably help the girl with the simple *herpes labialis* treatment, but she wasn't given any instructions how to take the medicine. But even with the given instructions she would be exposed to possible, and in this case totally unnecessary, side effects of aciclovir taken in high dose instead of local and less harm medicine application of ointment formulation. Even the friend pharmacist intention was to protect the reputation of the profession and the other colleague, let's not underestimate the patient's common sense and knowledge in order make the comparison between the services in cosmetics market and the pharmacy she visited. So, the possible consequence could be and mistrust to community pharmacies in general or consideration of them as a common retail stores, considering that judging by this case, nothing sets them apart.

CONTINUATION OR ESTABLISHMENT OF NEW PRACTICES

However, we have to discuss and mention possible reasons for dispensing pharmacist actions in this case. Was it to make more profit (having in mind that dispensed package of aciclovir tablets is 10 time more expensive than the aciclovir OTC ointment)? However, it could've happened because of the lack of available employees at the time, or newly employed personnel. [5] It could've been a pharmacy technician that dispensed aciclovir tablets without a prescription? None of the reasons is justified and it is in contrast with the moral and professional principles of pharmaceutical profession. So, this is the example of practices we must not support. As Vuković Rodriguez and Juričić have found in their study the pre-defined ethical scenarios experienced by the largest proportion of pharmacists are being asked to dispense a drug to someone other than the patient (93.3%), an unnecessary over-the-counter medicine (84.3%), a generic medicine clinically equivalent to the prescribed one (79.4%), or hormonal contraception over the counter (70.4%). [6]

POSSIBLE PROPOSALS FOR AMENDMENTS

Appropriate review of the contemporary moral and ethical dilemmas in the pharmacy profession in Bosnia and Herzegovina and their causal relationships would be useful in order to prevent further degradation of profession. Moral and ethics in community pharmacies is the value that separates community pharmacies from common retail stores. According to Puc the value is not added just through the products but also through information on one's health [7] and the pharmacists' knowledge and the quality of the pharmaceutical services should be the main pharmacy feature in visitors' eye. Continuous education and moral and ethics discussion is desirable including greater involvement of the competent chambers. Perhaps, the considerations of Holistic Community Pharmacy[®][8] concepts should be included for the future.

REFERENCES:

1. XI Registar lijekova Bosne i Hercegovine, ALMBiH 2020, available at <http://www.almbih.gov.ba/dokumenti/publikacije/> (accessed 21.08.2020.)
2. Law on Pharmaceutical Activity of Federation of Bosnia and Herzegovina, Official Gazette of the Federation BiH No. 40/10, Articles 37, 39 and 68, available at <http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-apotekarskoj-djelatnosti> (accessed 28.07.2020.)
3. Edina Stević et al. Dobra praksa propisivanja i izdavanja lijekova, Ministarstvo zdravstva Kantona Sarajevo, Institut za naučnoistraživački rad i razvoj KCUS, Sarajevo 2011. available at <http://judzks.ba/wp-content/uploads/2018/09/Dobra-praksa-propisivanja-i-izdavanja-lijekova.pdf> (accessed 27.08.2020)
4. Pharmaceutical Code of Ethics and Deontology, available at <http://komoramagistarafarmacije-tk.ba/akti-komore> (accessed 26.08.2020)

5. Irma-Hermina Klemenc, Can Community Pharmacy Uphold It's Moral Obligation to Act in Patient's Best Interest?, HCP-Transformation for the Future Conference, November 2019.
6. Vuković Rodriguez, J. Juričić, Ž. Perceptions and attitudes of community pharmacists toward professional ethics and ethical dilemmas in the workplace, Research in Social and Administrative Pharmacy, Volume 14, Issue 5, May 2018, Pages 441-450
7. Puc, M. Quality management in a community pharmacy, COVIRIAS 1st Edition, Ljubljana 2017 available at https://covirias.eu/wp-content/uploads/2019/04/COVIRIAS_Introducion_to_Quality_Management_in_Community_Pharmacy.pdf (accessed 25.05.2020)
8. Puc, M. 2017. Holistic Community Pharmacy – Declaration of Fundamental Principles of Holistic Community Pharmacy. Ljubljana: Covirias.

IS THE DIFFERENCE BETWEEN NUTRITION UNDER THE LABEL OF PRESCRIBED MEDICATION AND THE ONE COMING FROM FOOD SUPPLEMENTS ONLY BUREAUCRATICAL OR BIOLOGICAL TOO?

IRMA-HERMINA KLEMENC
Lekarna Dravlje

THE SITUATION IN QUESTION

A 45-years old woman, who was prescribed a treatment for iron deficiency, came in seek of advice to our pharmacy. Doctor prescribed her a medication containing ferrous sulfate. The aforementioned is known for possible cause of some side effects regarding stomach pain, diarrhea or constipation, upset stomach and throwing up. As it happens, she has been having problems with empty ferrous stores all her life. Sometimes iron deficiency comes about even so often as two to three times per year. However, it has always been hard for her to stay compliant with iron containing medication, due to unbearable stomach pain and irritable bowel. Only a month after the conclusion of her last treatment for iron deficiency, she started feeling fatigued, exhausted and irritable. She has been diagnosed with anemia once again. As the woman came to our pharmacy, she expressed doubt of her being able to follow through the prescribed therapy for anemia once again. It seems to her that for the period of few months when she is struggling to be compliant with iron containing medication despite her stomach problems, iron stores in her body are refilled. But as soon as her medication is used up her iron deficiency expresses itself afresh. It would be imperative for her to be able to continuously persist with iron substitution.

REGULATION

Prescription drugs are by the Medicinal Products Act in Republic of Slovenia defined as substances intended to treat, diagnose, or prevent disease for human or veterinary use. Rules on the classification, prescribing and dispensing of medicinal products for human use in EU, regulate the list of conditions adequate for self-medication and self-treatment with medicinal products. European commission directive defines "food supplements" as foodstuffs for the purpose to supplement normal diet, which are concentrated sources of nutrients/other substances with nutritional or physiological effect, alone or in combination, marketed in dose forms such as capsules, pastilles, tablets, sachets of powder, ampoules of liquids etc. According to valid pharmaceutical code of deontology in

Republic of Slovenia, community pharmacists should strive for continuous improvement of services and products, and to make decisions that contribute to the development and reputation of pharmaceutical profession and pharmaceutical science. (1, 2, 3, 4)

OBSERVED PRACTICE

In Canada under the Natural Health Products Regulations, Dietary Supplements (DS) are defined as "substance that is manufactured or sold for use in: diagnosis, treatment or prevention of a disease, disorder or abnormal physical state or its symptoms; restoring/correcting organic functions; modifying organic functions in a manner that maintains/promotes health". Under the new regulations, all DSs will require a product license before they can be sold in Canada. Approval for sale is granted by Health Canada, based on several tiers of evidence of safety and efficacy. However, there is still a strong agreement among Canadian pharmacists for the need to have additional training on DS. In a national survey, 92% of Canadian pharmacists said they feel the study of nutraceuticals should be mandatory in the pharmacy curriculum. On the contrary US pharmacist recommendations of supplement products were found to occur on average 4.9 times per month, with 164 respondents making no recommendations at all. In a Texas study, pharmacists had documented the use of alternative therapies in the patients' pharmacy records in only 11% of the cases. Moreover, 45% of pharmacists did not monitor patients' use of alternative therapies. Similarly, only 24% of pharmacists from California, stated that they routinely maintained a record of complementary supplements taken by their patients. (5, 6, 7)

THE DILEMMA

Through my concern for the woman's concordance with her iron deficiency therapy, I advised her to implement an iron Food Supplement in her daily routine. On what ground could someone label iron in prescription medications as being better to the one in Food Supplement? The truth of the matter is that our organism is unaware of the difference, whether the needed nutrition is packed as prescription medication or labelled as Food Supplement. If the iron integrated in Food Supplement is better accepted by our organism, what importance does labelling something as prescription medication hold? Nevertheless, I wanted to support her decision to at least give her prescribed therapy a try. If it would cause her to experience stomach ache again, she could continue refilling her ferrous stores only by given Food Supplement. I decided to offer her a Food Supplement based on iron isolated from herbs and plants. This form of iron seems to very unlikely be able to cause digestion problems. She decided to endeavor iron Food Supplement in form of a syrup as well as in capsules, in order to stay more adherent with her treatment. Finally, the herbs from iron Food Supplement also contain a fair amount of vitamin C and B-complex that should help with body's absorption of iron, with no need for additional combination with other supplements. Long term absence of digestion problems would give her an opportunity to continue her treatment longer than few months.

CONSEQUENCES

Over the last decade governments as well as the public across EU countries have become conscious of evident benefits on overall health and human development that different nutrition has, given in right amounts during specific lifetime's periods. For example, it has become a known fact that folic acid decreases the risk of birth defects taken during pregnancies, that combination of zinc, copper and lutein slows down further vision loss in people with age-related macular degradation, or that vitamin D manages the correct development of bones in infants. In several EU and US surveys, it has been argued that pharmacists could be instrumental in helping patients make safe and informed choices about Food Supplement. Moreover, there is evidence to show that patients in US and Canada view pharmacists as trustworthy and knowledgeable about Dietary Supplements. For example, in one US study, 37% of the respondents agreed that pharmacists' advice is important for alternative therapies with DS. The American Society of Health-System Pharmacists (ASHP) urges pharmacists to "integrate awareness of dietary supplement use into everyday practice". Moreover, an information paper, The Role of the Pharmacist with Respect to Complementary/Alternative Medicine suggests: "Our role as pharmacists is to help educate patients about Dietary Supplements and to guide them to make informed choices. Our goal should be to ensure that patients who choose to use Dietary Supplementsto do so safely".(4, 10,11)

CONTINUATION OR ESTABLISHMENT OF NEW PRACTICES

The newest survey data indicates that Canadian pharmacists are more likely to recommend Dietary Supplements, since the new official regulation of Dietary Supplements was implemented in their country. Furthermore, latest studies found that Canadian pharmacists discussed with physician use of a Dietary Supplements instead of medicinal drug almost 40 % more often, since the pass of the new regulation. However, there is a strong agreement among Canadian pharmacists for the need to have additional training on Dietary Supplements. Furthermore, pharmacists ranked interactions (84 %), side effects (80 %), patient counselling (71 %), therapeutic uses (68 %), and dosing (59%) of DS as "very important" knowledge. One US study found that most pharmacists agreed that continuing education on supplement self-medication should be mandatory. Several surveys in 2015 found that 43 % of Canadians are most likely to say that they completely trust the DS information provided by their pharmacists and 18 % identified pharmacists as primary sources of information on Dietary Supplements. (8, 9, 12)

POSSIBLE PROPOSALS FOR AMENDMENTS

Since pharmacists are readily accessible to patients at the point where they are making decisions about purchasing Food Supplements, pharmacists are in a good position to provide patients with evidence-based information about Food Supplements, especially regarding potential interactions with conventional medications. Pharmacists also have

the knowledge and experience to help patients determine when self-medication is appropriate and when the expertise of another healthcare provider is needed. Training in pathophysiology and pharmacology provides pharmacists with the necessary background to interpret and evaluate studies of Food Supplements and theoretically places them in an excellent position to determine, whether a Food Supplement is a safe and appropriate option, given any other medication a patient may be taking. Recognizing that pharmacists have an opportunity to develop a unique and credible professional role for themselves as expert advisers on Food Supplements, professional associations, such as the American College of Clinical Pharmacy, the American Society of Health-System Pharmacists, and the Canadian Society of Hospital Pharmacists, have recommended that the profession of pharmacy actively embrace Dietary Supplements as part of the pharmacist's scope of practice. The Canadian practice of unified approach to categorization and quality control in the field of Dietary Supplements shows us that stronger control over supplement market is possible. I believe that improved control over Food Supplements quality also encourages the manufacturers of medications to upgrade their products. In recent years, particularly manufacturers of Food Supplements are trying numerous reformed projects in order to exceed in quality due to fierce competition among them. In my opinion community pharmacy in Slovenia could learn a lot from Canadian practice. Valid code of deontology in Republic of Slovenia dictates that pharmaceutical professionals should encourage the acquisition and exchange of expertise and skills to ensure professional advancement and a high level of patient care in all settings. (3, 10, 11, 12)

REFERENCES

1. Zakon o zdravilih/ZZdr-1/2006, 5. člen (od.1, 2) Uradni list RS, št 31/2006 (24.3.2006), (Medicinal Products Act-1)
2. Directive 2002/46/EC of the European Parliament and of the Council of EU, Article 2(a) Official Journal L 183 (12.7.2002, P. 0051 - 0057)
3. Kodekslekarniškedeontologije, (3) člen 21, 23, Uradni list RS, št. 85/2016 in 77/2017 (19.6.2019), (Code of deontology)
4. The Rules governing Medicinal Products in the European Community Volume 2C: Guidelines, European commission, 2006
5. Natural Health Products Regulations, Canada Gazette Part II, 2003, Her Majesty the Queen in Right of Canada, 137 (13)
6. Dolder C, Lacro J, Dolder N, Gregory P: Pharmacists' Use of and Attitudes and Beliefs about Alternative Medications, American Journal of Health-System Pharmacy, 2003, 60: 1352-1357
7. Brown CM, Barner JC, Shah S: Community Pharmacists' Actions When Patients Use Complementary and Alternative Therapies with Medications, Journal of the American Pharmacists Association, 2005, 45 (1): 41-47
8. Health-Canada: Baseline Natural Health Products Survey Among Consumers
9. Chang ZG, Kennedy DT, Holdford DA, Small RE: Pharmacists' Knowledge and Attitudes Toward Herbal Medicine; The Annals of Pharmacotherapy, 2000, 34: 710-715

10. Kroll DJ: ASHP Statement on the Use of Dietary Supplements; American Journal of Health-System Pharmacy, 2004, 61: 1707-1711
11. Boon H: CSHP Official Publications; 2001, Ottawa, Canadian Society of Hospital Pharmacists, 181-186, Information Paper: The Role of the Pharmacist with Respect to Complementary/Alternative Medicine, Pharmacists CSH, CSHP Official Publications, Alternative Medicine Task Force CSHP
12. Boon H: CAM and Pharmacists: Challenge or Opportunity? Focus on Alternative and Complementary Therapies; 2005, 10 (2): 1-3

THE ETHICS IN SELF- MEDICATION OF CHRONIC HEART FAILURE

NINA STRAH, MATIJA CENTRIH
Lekarna Dobrova

THE SITUATION IN QUESTION

After 65-years old woman comes to a community pharmacy, we immediately notice her shortness of breath. She asks for midland hawthorn tea. She admits the usage of the herbal remedy for four weeks now. However, she claims that her symptoms are not improving. She admits buying the tea in another pharmacy. We do not have midland hawthorn tea in our offer. She tells us that her feet and ankles are usually swollen when she does not lay in bed. Moreover, she describes the usage of an extra pillow underneath her head while sleeping. Otherwise, her breathing is aggravated. Midland hawthorn tea was recommended by her friend, so she decided to give it a try.

Midland hawthorn (*Crataegus laevigata*), also known as haw, thornapple, maythorn, whitethorn, has an extended traditional use for its cardioactive effect.^{1,2} According to European Union herbal monograph on *Crataegus* spp., folium cum flore³ the use is strictly traditional, and the herbal remedy can be found in different forms: comminuted herbal substance, powdered herbal substance, dry and liquid extract, expressed juice from the fresh leaves and flowers and tincture. Two indications are mentioned, symptoms of temporary nervous cardiac complaints and mild sleep and nervousness problems. However, both of them need a doctor's evaluation.³

REGULATION

Symptoms of heart failure are not specific; therefore, the diagnosis of heart failure must be made by a cardiologist. The diagnosis starts with the plasma concentration of the natriuretic peptide. Next, they check electrocardiogram and echocardiography. These three tests can provide enough information for the first therapy. The recommended medicines for heart failure are Angiotensin-converting enzyme inhibitors, beta-blockers, and mineralocorticoid/aldosterone receptor antagonists.⁴ All listed medicines are legally available only on a prescription. Allowed cure or ease of symptoms of diseases without a need for medical attention in OTC regime are legally specified. Self-medicated indications are: mild pain, cough, simple cold, runny nose, oral infection, boosting immunity, infections of urinary tract, digestive problems, skin inflammation, menstrual and menopausal problems, stomach problems, diseases of periphery vasculature, help with losing weight, curing and preventing unhealthy habits.⁵

OBSERVED PRACTICE

Herbal remedy midland hawthorn is available in different forms (dry and liquid extracts and comminuted herbal substance). The comminuted herbal substance is usually prepared as a water infusion. Patients should prepare their infusions and drink them, according to given instructions.^{6–9}

All products have the same way of preparation. The patient should measure 1 to 2 teaspoons of herbal drug and pour over 200 ml of boiling water. The infuse should sit for 15 to 20 minutes. All declarations claim that herb's active ingredients increase the contraction force of cardiac muscle, increase the heart blood circulation, and provide a mild blood pressure drop. ^{6–9} However, three of them also include the officially labeled indication: the symptoms of temporary nervous cardiac complaints.^{3,6,7,9} All forms: comminuted herbal substance, liquid, and dry extracts, have a warning that patients should see the doctor before using the remedy. The most prolonged period of use is six weeks. Nevertheless, the products are available without prescriptions, and are not labeled as medicines.

THE DILEMMA

The first concern is an accurate diagnose and a medical supervision of individual reactions for a condition inappropriate for self-medication. Moreover, none of the products has a qualitative and quantitative analysis of active ingredients. The patient may use 1 to 2 teaspoons of dry herb. However, there are no criteria when one teaspoon and when two teaspoons are needed. The quantity is the patient's subjective decision since the symptoms cannot be measured with numbers. Also, the size of teaspoons varies. Additionally, some patients may use a full spoon; some leveled with the edge. One teaspoon roughly brings 3 grams of the herb, a full teaspoon a bit more. That means that some patients decide to take 3 grams and some 6 grams of the tea preparation. Some prepare tea for 15 min and some for 20 min. The tea may be drunk 3 to 4 times per day. The variation of active ingredients content seems significant. In addition, mechanisms are not clear. Antioxidant activity, positive inotropic action, anti-inflammatory, antiplatelet aggregation, vasodilating, and endothelial protective properties, reduction of smooth muscle cell migration and proliferation, protective effect against ischemia/reperfusion injury, antiarrhythmic effect, lipid-lowering properties, and decrease of arterial blood pressure are all possible hypothesis how midland hawthorn contributes to the improvement of cardiovascular function. Moreover, all outcomes were confirmed only in animal models.¹⁰

CONSEQUENCES

Heart failure has symptoms that are not specific enough for self-medication. It may happen that patient with swollen ankles has completely different diagnose. Therefore, the visit of a medical doctor is more than necessary. However midland hawthorn tea is available without a prescription. They can drink tea without any consultations and delay

the diagnosis. Even considering the patient indeed suffers from chronic heart failure, the precise regulation of active compounds with the tea is impossible. As described above, there are several ways to prepare tea, and the variation of ingredients is always different. The analysis of teas prepared with teabags showed variables. Some ingredients' content also differed for 10%, and some were present in less than 1%.¹⁰ First, for now, none can point out the real active ingredient, and second, the content is variable. Consequently, the disease cannot be controlled, considering that even official therapy is not fixed.⁴ Other diseases with similar symptoms such as chronic lung disease may need urgent intervention.⁴ The duration of treatment with hawthorn is approximately 4 to 6 weeks.^{6–9} Consequently, the patient would not visit the doctor in the next 1 to 2 months, which can make a difference in the therapy outcome.

CONTINUATION OR ESTABLISHMENT OF NEW PRACTICES

Heart failure is a progressive disease. With time the condition worsens despite clinical care. It demands a lifelong therapy and, in general, just prolongs and eases the patient's life. Heart failure syndrome affects more than 23 million people worldwide. The epidemic massively impacts the quality of life, functioning, and longevity, while foisting high costs on the health care system.¹¹ The exact costs are different from country to country and range from \$868 for South Korea to \$25,532 for Germany per patient. What is more, the costs rise 8 to 30 folds when the diseases progress. However, in the calculation costs of home care for patients (e.g., by non-professionals) are not included.¹² The possibility of self-diagnosis and self-treatment can lead to a higher mortality rate, and the costs of health care would be much higher. It is unethical and illegal to have products, specifically midland hawthorn tea, available without a prescription and registration.

POSSIBLE PROPOSALS FOR AMENDMENTS

Why midland hawthorn should be tightly regulated is explained by the fact that it is a medical plant. In this case, the European Medicines Agency (EMA) is responsible for assessing herbal products' safety and efficacy. The Directive 2004/24/EC established that a herbal medicinal product is "any medicinal product, exclusively containing as active ingredients one or more herbal substances, or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations".^{10,13}

Furthermore, the doctor's visit must be mandatory. Patients with signs of heart failure or similar diseases should be forced to visit their doctor and get the proper diagnose and therapy including supervision. There is already an established practice in Germany, where patients with heart failure can also get midland hawthorn extract under certain conditions.¹

Complementary law¹⁴ in addition oblige community pharmacies to immediately remove all midland hawthorn tea preparations. In line with professional knowledge and ethic awareness competent authorities should be informed to clean the market outside pharmacies.

REFERENCES

1. Orhan, I. E. Phytochemical and Pharmacological Activity Profile of *Crataegus oxyacantha* L. (Hawthorn) - A Cardiotonic Herb. *Curr. Med. Chem.* 25, 4854–4865 (2018).
2. HerbalGram: Hawthorn: A LITERATURE REVIEW. <http://cms.herbalgram.org/herbalgram/issue22/article463.html?ts=1597219361&signature=423df3b19fe51bba3e501ba6d490eed5>.
3. European Union herbal monograph on *Crataegus* spp., folium cum flore. 7.
4. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure | *European Heart Journal* | Oxford Academic. <https://academic.oup.com/eurheartj/article/37/27/2129/1748921>.
5. Pravilnik o razvrščanju, predpisovanju in izdajanju zdravil za uporabo v humani medicini. pisrs <http://pisrs.si>.
6. Glog zdravilni čaj - Srce in ožilje - Gorenjske lekarne. <https://www.gorenjske-lekarne.si/artikel/glog-zdravilni-caj>.
7. GLOG 100 g | Goriška Lekarna. <https://www.goriskalekarna.si/galenski-laboratorij-nova-gorica/izdelki-galenskega-laboratorija/glog-100-g>.
8. Glog. Dolenjske Lekarne <https://www.dolenjske-lekarne.si/enokomponentni-caji/glog/607908>.
9. Mariplant List in cvet gloga čaj. <http://www.prvalekarna.com/izdelki/mariplant-list-in-cvet-gloga-caj>
10. Nunes, M. A., Rodrigues, F., Alves, R. C. & Oliveira, M. B. P. P. Herbal products containing *Hibiscus sabdariffa* L., *Crataegus* spp., and *Panax* spp.: Labeling and safety concerns. *Food Res. Int.* 100, 529–540 (2017).
11. Chaudhry, S.-P. & Stewart, G. C. Advanced Heart Failure: Prevalence, Natural History, and Prognosis. *Heart Fail. Clin.* 12, 323–333 (2016).
12. Lesyuk, W., Kriza, C. & Kolominsky-Rabas, P. Cost-of-illness studies in heart failure: a systematic review 2004–2016. *BMC Cardiovasc. Disord.* 18, 74 (2018).
13. Organization, W. H. WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues. (World Health Organization, 2007).
14. Zakon o lekarniški dejavnosti. pisrs <http://pisrs.si>.

DISPENSING CRATAEGUS TEA PRODUCTS FOR SELF-MEDICATION

ANA DEŽELAK
Lekarna Dravlje

THE SITUATION IN QUESTION

Hawthorn dried leaves and flowers can be bought in pharmacies in order to relieve symptoms of temporary nervous cardiac complaints. (1, 2) However, serious dilemmas rise up, if it is appropriate to use this herbal medicinal product for self-medication. Self-medicating drug should not require physician's monitoring during therapy, should not have unfavorable profile of adverse effects and should not interact with commonly used medicines or foods. (3) These medicines are intended to be used by costumers on their own responsibility. (3, 4) For over the counter medicines, which are being sold solely in pharmacies, safe self-medicating process includes supervision and counseling of pharmacists. (4)

If medical practitioner is not included in this process, various diagnostic investigations won't be executed. As a consequence, the underlying cause of cardiac disorder cannot be defined. (5)

REGULATION

Crataegus spp. Herbal tea is in Slovenia officially classified in the group Z of medicinal herbs' list. This group is mainly reserved for herbal drugs, which are dispensed without medical prescription. (6) "Rules on the classification, prescribing and dispensing of medicinal products for human use" describe when it is appropriate to use these medications:

Article 13 states that medicinal products dispensed without medical prescription are meant to treat self-diagnosed disorders or symptoms. Their role is to treat conditions which do not require medical attention. The user should be very certain about his symptoms, otherwise he can have crucial consequences, as the treatment is not optimal. In the Article 20, indications appropriate for self-medication are listed. The list does not contain cardiovascular-related issues. (4)

OBSERVED PRACTICE

European Medicines Agency (EMA) has approved the use of hawthorn leaf and flower as traditional medicinal herbal product. It can be used to relieve symptoms of temporary

nervous cardiac complaints after thorough medical examination has been done, if the symptoms do not persist for longer than 2 weeks. The second indication are mild mental problems and sleeping disorders. To prepare herbal tea 1-2 g of the comminuted herbal substance should be mixed with 150 ml of boiling water and consumed as a herbal infusion up to 4 times daily (max. 6 g). (2) Hawthorn herbal tea is in Slovenia categorized as non-prescriptive medicine. It can be bought in pharmacies as well as online. (1, 6) In some countries (Austria, Germany, Czech Republic, Lithuania) hawthorn herbal tea is used as a prescription medicine. In these cases, they have warnings, such as: "An adjuvant in mild forms of hypertension, for heart blood flow improvement, for support of heart function; consultation with a doctor is needed before the first use." (7)

THE DILEMMA

By the 11th article of Codex of Pharmaceutical Deontology of Slovene Chamber of Pharmacy, pharmacists should make sure that treatment for the patient is of good safety, quality and efficacy. (8) It is against the law to give patients a medicinal product for heart related issues without a valid marketing authorization and without a prescription. (4)

Is it safe if we treat patient's heart deficiency symptoms with Crataegus herbal tea, when it is recommended that conditions connected to decreased cardiovascular function are monitored by the doctor (9)? There is no database on side effects of these products or on deaths connected to their intake.

CONSEQUENCES

Some of serious heart conditions are asymptomatic, therefore it is hard to state, without medical examination, that specific condition is not dangerous. Cardiac disorders should be taken seriously as symptoms can change rapidly and sometimes quick deterioration ends with hospitalization or even death. (5)

Herbal product of hawthorn should be dispensed and used with precaution. If the ankles or legs become swollen, when pain occurs in the region of the heart, which may spread out to the arms, upper abdomen or the area around the neck, or in case of respiratory distress (dyspnea), a doctor or a qualified health care practitioner should be consulted immediately. (2) Consuming hawthorn preparations increases the risk of adverse effect through herb-drug interaction. (10) However, the interaction cannot be predicted, as the source and quality of raw material is not known. Moreover, plants are usually mixtures of active components. The exact content is not known, because composition of herbal medicines differs from harvest to harvest, geographical location, drying and storage. (11)

CONTINUATION OR ESTABLISHMENT OF NEW PRACTICES

There exist many more convenient options that a patient can perform on his own initiative, which will help to prevent heart disease: weight control, dietary measures, smoking cessation, other pharmacological interventions, ... (10) Secondly, if the categorization of some other countries (mentioned above) is followed (7), manufacturers could register these medicinal products as prescription medicines in order to manage potential risks.

POSSIBLE PROPOSALS FOR AMENDMENTS

The use of Crataegous preparations should be limited to the functional symptoms of a healthy heart, confirmed by a clinical and electrocardiographic check-up. (7) All the above-mentioned dilemmas concerning self-medication apply also for other hawthorn's preparations. The most common ones are ethanol or water extracts in different ratios. These are usually standardized and variability is therefore smaller. (2, 11)

Crataegous herbal tea is not the only substance on the market, belonging to the group Z and at the same time to the group of preparations which are intended to be used when symptoms connected to heart disease appear. Another similar case is *Viscum album*, for example. (6, 12, 13). It is important that pharmacists maintain their professionalism when dispensing these medicinal products, which means that they are aware of responsibilities and limitations. Competent authorities should give in writing their official opinion on the marketing of these products without authorization and without prescription.

REFERENCES

1. Online pharmacy, Glog zdravilni čaj, <https://www.gorenjske-lekarne.si/artikel/glog-zdravilni-caj>, Accessed 30 August 2020.
2. EMA/HMPC/159075/2014 Committee on Herbal Medicinal Products (HMPC), European Union herbal monograph on *Crataegus* spp., folium cum flore Final, 5 April 2016.
3. WHO Guidelines for the regulatory assessment of medical products for use in self-medication, 2000.
4. Rules on the classification, prescribing and dispensing of medicinal products for human use, Uradni list RS, št. 86/08, 45/10, 38/12 in 17/14 – ZZdr-2.
5. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure, 2012.
6. Agency for medicinal products and medical devices of the Republic of Slovenia, Guidelines for the definition of products which may at the same time fall into the definition of the medicinal product and the product subject to other regulations for human use, March 2018.
7. EMA/HMPC/159076/2014 Committee on Herbal Medicinal Products (HMPC), Assessment report on *Crataegus* spp., folium cum flore Final, 5 April 2016.
8. Slovene Chamber of Pharmacy, Codex of Pharmaceutical Deontology, 19 June 2019.

9. EMA/HMPC/150876/2015 Committee on Herbal Medicinal Products (HMPC), Overview of comments received on European Union herbal monograph (EMA/HMPC/159075/2014) and European Union list entry (EMA/HMPC/685372/2014) on *Crataegus* spp., folium cum flore Final, 5 April 2016.
10. Guo R, Pittler MH, Ernst E. Hawthorn extract for treating chronic heart failure. *Cochrane Database of Systematic Reviews* 2008, Issue 1. Art. No.: CD005312.
11. Kunle, F Oluyemisi, Egharevba, O Henry, Ahmadu&O Peter, Standardization of herbal medicines -A review. 2012, *International Journal of Biodiversity and Conservation*. 4. 101-112.
12. Online pharmacy, Bela omela zdravilni čaj, <https://www.gorenjske-lekarne.si/artikel/bela-omela-zdravilni-caj>. Accessed 30 August 2020.
13. EMA/HMPC/246778/2009, Committee on Herbal Medicinal Products (HMPC), Assessment report on *Viscum album* L., herba , Final, 20 November 2012