

COVIRIAS

CONTEMPORARY ETHICAL AND  
MORAL DILLEMAS IN COMMUNITY  
PHARMACY'S PRACTICE  
ON HCP 2021



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CONTEMPORARY ETHICAL AND MORAL DILEMMAS IN COMMUNITY  
PHARMACY'S PRACTICE ON HCP 2021

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## PREDGOVOR ORGANIZATORICE IN POBUDNICE HCP KONFERENCE<sup>1</sup>

Etične in moralne dileme v lekarni se tudi v tretjem HCP (Holistic Community Pharmacy<sup>®</sup>) konferenčnem letu 2021 predstavljajo kot uvodna tema oz. temelj lekarništva v zdravstvenem sistemu.

Pomen etike in morale je odvisen od opredelitve vloge posameznika oziroma poklica in dejavnosti. Zato je potrebno izpostaviti, s kakšno vlogo se identificira vsak posamezen lekarniški farmacevt in lekarna. Če je lekarna proizvajalec ali distributer, ima seveda popolnoma drugačne interese, kot če se sebe razume in deluje kot osrednja točka svetovanja za ohranjanje in izboljševanje zdravja posameznikov v lokalni skupnosti. Podobno velja za posameznega lekarnarja. Če se ta identificira z vlogo proizvajalca in se fokusira na zdravilo kot izdelek, to prinese drugačno vedenje, odločanje, zaznavanje težav in dileme kot jih prinese fokus na reševanje zdravstvenih vprašanj posameznika, ki vstopi v lekarno. Glede na lastno identiteto oziroma razumevanje svoje vloge lahko lekarnar pri svojem delu posveča svojo pozornost predvsem izdelkom ali pa se osredotoči bolj na obiskovalce lekarne z individualnimi težavami in zdravstvenimi okoliščinami.

Dilemo imamo, ko izbiramo med dvema ali več možnostmi, katera imajo vsaka svoje prednosti in slabosti. Pri etičnih in moralnih dilemah so ravno slabosti različnih izbir dokaj uravnotežene. Pri tem igra pomembno vlogo znanje in zavedanje, koliko možnosti sploh imamo, kot tudi sistem vrednot, ki vpliva na izid, kaj pretehta pri našem izboru. Pri lekarniški storitvi imamo v prvi vrsti na eni strani zelo jasen interes izvajalca (neposredni finančni vpliv, poraba časa, energije, potrebne kompetence zaradi kompleksnosti, soočanje z neznanjem, prepričanji ipd.), na drugi strani pa interes uporabnika storitve (doprinos k zdravju, varnost, učinkovitost, vpliv na življenjski slog, finančna obremenitev). V ozadju pa je še interes proizvajalcev distributerjev, zavarovalnic in drugih deležnikov. Ključno vprašanje je, kdo odloča med različnimi možnostmi in na podlagi katerih kriterijev. Zaradi neenakopravnosti med izvajalcem in uporabnikom storitev zaradi različnih znanj in prepričanj ter informiranosti lahko izvajalec storitve hitro pride v skušnjava, da bi se odločil namesto uporabnika storitve. Opredelitev odgovornosti izvajalca storitve ter pacientovih oziroma potrošniških pravic je pokrita z raznoliko zakonodajo in dogovori, npr.:

- [The Nuremberg Code 1947](#)
- [Declaration of Helsinki](#)(adopted in 1964, last updated 2013)
- [UNESCO's Universal Declaration on Bioethics and Human Rights \(2005\) International Ethical Guidelines for Health-Related Research Involving Humans \(fourth version published 2016\)](#)

<sup>1</sup> V prvih dveh letih smo ugotovili, da imajo lekarniški farmacevti težave pri udeležbi na HCP konferenci zaradi izvedbe v angleškem jeziku. Da bi omogočili lažje spremljanje predstavljenih vsebin in vključevanje čim več zainteresiranim, smo letos pripravili kombinirano obliko tako samih srečanj, kot tudi pričujoče spremne publikacije.

- Ustava Republike Slovenije (Uradni list RS, št. 33/91-I, 42/97 – UZS68, 66/00 – UZ80, 24/03 – UZ3a, 47, 68, 69/04 – UZ14, 69/04 – UZ43, 69/04 – UZ50, 68/06 – UZ121,140,143, 47/13 – UZ148, 47/13 – UZ90,97,99, 75/16 – UZ70a in 92/21 – UZ62a)
- Zakon o lekarniški dejavnosti (Uradni list RS, št. 85/16, 77/17 in 73/19)
- Zakon o zdravilih (Uradni list RS, št. 17/14 in 66/19)
- Uredba o izvajanju uredbe (EU) o medicinskih pripomočkih (Uradni list RS, št. 16/18)
- Zakon o zdravstveni ustreznosti živil in izdelkov ter snovi, ki prihajajo v stik z živili (Uradni list RS, št. 52/00, 42/02 in 47/04 – ZdZPZ)
- Obligacijski zakonik (Uradni list RS, št. 97/07 – uradno prečiščeno besedilo, 64/16 – odl. US in 20/18 – OROZ631)
- Zakon o lekarniški dejavnosti (Uradni list RS, št. 85/16, 77/17 in 73/19)
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Pri tem moramo ločiti med zakonitostjo in pravno opredelitvijo dejavnosti, strokovnostjo (formalno znanje in strokovne kompetence) ter etiko in moralo (vidik uporabnika, kolegi, družba), ki se med seboj ne prekrivajo popolnoma. Pomembne razlike in podobnosti med njimi vključujejo različne posledice, če vsako od teh dimenzij lekarne in lekarnarji bodisi spoštujejo ali kršijo, oziroma kakšne koristi oziroma škodo prinaša spoštovanje oziroma kršenje zakonodaje, strokovnih norm oziroma etike in morale posameznemu uporabniku storitev in kakšne družbi.

Na področju dejavnosti in posameznih skupin izdelkov zakonodaja določa kar nekaj omejitev, z namenom zaščite potrošnika oziroma bolnika. V Zakonu o lekarniški dejavnosti se na primer 3. člen in 18. člen nanašata na omejevanje pospeševanje prodaje. Omejitev samozdravljenja pri tem velja ne glede na to, kdo zdravilo izdelava. Tako velja 20. člen Pravilnika o razvrščanju, predpisovanju in izdajanju zdravil za uporabo v humani medicini (Uradni list RS, št. 86/08, 45/10, 38/12 in 17/14 – ZZdr-2) tudi za galensko izdelana zdravila.

Ali je protizakonito delovanje (neizpolnjevanje zakonskih zahtev ali njihova zloraba) etično in moralno, ne da bi do njega zavzeli tudi strokovno stališče?

Upoštevati moramo tudi konflikt oziroma nasprotje ali navzkrižje interesov. Zakon o integriteti in preprečevanju korupcije (ZIntPK) nasprotje interesov definira kot "okoliščine, v katerih zasebni interes uradne osebe ali osebe, ki jo subjekt javnega sektorja imenuje kot zunanjega člana komisije, sveta, delovnih skupin ali drugega primerljivega telesa, vpliva ali ustvarja videz, da vpliva na nepristransko in objektivno opravljanje njenih javnih nalog. Zasebni interes osebe pomeni premoženjsko ali nepremoženjsko korist zanjo, za njene družinske člane in za druge fizične ali pravne osebe, s katerimi ima ali je imela ta oseba ali njen družinski član osebne, poslovne ali politične stike." V lekarništvu je potrebno biti še posebej pozoren na navzkrižje javnega in zasebnega interesa, nepotizem, klientelizem ter kronizem, kar so pomembne teme za obravnavo pristojne komisije na Lekarniški zbornici.

Kot je zaslediti iz javnih objav, se raziskovalci na področju etike in morale v zdravstvu ukvarjajo predvsem z odnosom med zdravniki in farmacevtsko industrijo (podkupnine, darila, financiranje strokovnega udejstvovanja)<sup>2</sup>. Ugotavljajo, da gre za vpliv ne le na strokovne odločitve, ampak tudi na same raziskave, ki vplivajo na oblikovanje pravil v družbi<sup>3</sup>. Prepoznavajo razširjen konflikt interesov, v kontekst katerega se postavljajo distributerji, zavarovalnice<sup>4</sup>,...

Sporne situacije lahko prenesemo na lekarništvu<sup>5</sup>, pri čemer sta ključni predvsem dve vprašanji:

- Na podlagi katerih kriterijev se izbira izdelke v ponudbi?
- Na podlagi katerih kriterijev se priporoča izdelke posamezniku?

Posebnost v lekarništvu je prekrivanje različnih vlog lekarne kot institucije, identifikacija nosilca odgovornosti za etično in moralno delo. Pričakovali bi, da se lekarnarji ukvarjajo s tehtanjem moralnih in etičnih dilem prav prej navedenih tem.

Trenutno lahko dvomimo o obstoju etike in morale v lekarništvu, ker javnosti ni predstavljeno delo pristojnih institucij ali samih lekarn na tem področju<sup>6</sup>. Napredek lahko dosežemo z ozaveščanjem stroke in javnosti. Vsak razmislek, še posebno skupinski, dolgoročno vodi v napredek, kar je vodilo za delo COVIRIAS academie na tem področju. Zahvalo celotne družbe pa si zasluži prav vsak izmed lekarnarjev, ki je dal tem prizadevanjem aktivni prispevek.

MAG. SCI. MARTINA PUC MAG. FARM., SPEC., MBA

USTANOVITELJICA COVIRIAS ACADEMIE IN AVTORICA KONCEPTA HOLISTIČNA LEKARNA

<sup>2</sup>Rodwin, Marc A. 2011. "Reforming Pharmaceutical Industry-Physician Financial Relationships: Lessons from the United States, France and Japan." *Journal of Law, Medicine and Ethics* 39(4): 662–670.

<sup>3</sup>Ugotavljajo, da gre za vpliv ne le na strokovne odločitve, ampak tudi na same raziskave, ki vplivajo na oblikovanje pravil v družbi.

<sup>4</sup>Prepoznavajo razširjen konflikt interesov, v kontekst katerega se postavljajo distributerji, zavarovalnice,...

<sup>5</sup>Pharmacists, pharmaceutical manufacturers, and conflicts of interest

David Banks, B.S.Pharm., Ph.D. *American Journal of Health-System Pharmacy*, Volume 62, Issue 17, 1 September 2005, Pages 1827–1832, <https://doi.org/10.2146/ajhp040504> Published:01 September 2005

<sup>6</sup>Izjema so prispevki v okviru HCP konferenc, ki so javno objavljeni: Transformation for the Future, 2019 in Contemporary ethical and moral dilemmas in Community Pharmacy's practice, 2020.



## SHOULD PHARMACISTS DISPENSE MEDICINE TO A COURIER WHO CANNOT PROVIDE SUFFICIENT INFORMATION ABOUT THE PERSON IN NEED?

ANA DEŽELAK  
LEKARNA DRAVLJE

Visitors repeatedly come to a pharmacy in order to buy medicines for other people. The occurrence is not known, however, it happens occasionally, that they are only in the role of a courier and know very little about the lifestyle, health state and symptoms of the person who supposedly needs a certain medicine.

The basis for a selection of agents to treat health issues is the result of an interpretation of information that the final user has. (TV or newspaper advertisement, neighbor's experience, previous events, ...) First questions that arise are whether the person in need is able to recognize his symptoms and knows best what the optimal solution of his health-related problems is. However, we also have to take into account possible contraindications and interactions (2).

Pharmacists or pharmacy technicians are the ones, who interact with the courier and try to fulfill their obligation to act in patient's best interest. Should the "wanted" medicine be dispensed even though we do not have enough information whether the selection of this medicine is appropriate.

Operating with all the knowledge and professional experience, pharmacists have solutions, (other treatment options and lifestyle changes, food supplements), which could have better long-term health outcomes. (1)



Comparative regulation in other countries preferred. The 3rd article of Pharmacy Practice Act in Slovenia states that pharmacist is responsible for appropriate use of medicinal products and other products which complement treatment or maintain health.

Pharmacists should prevent misuse of medicines and other products, which maintain health. We should prevent possible health issues and damage, which can arise if the medicine is not taken correctly. (2) Above mentioned rules are following Joint FIP/WHO Guidelines on Good Pharmacy Practice. Well-being of patients should be the main philosophy underlying practice. Pharmacists should have an input into decisions about the use of medicines. (1)

According to the 60th Article of Rules on the classification, prescribing and dispensing of medicinal products for human use, pharmacists can refuse to dispense OTC medicines if there is a chance of drug abuse. (3)

On a daily basis it happens that a person comes to a pharmacy and seeks medicines for another person. Every visit is accompanied with basic questions in order to pharmacists get familiar with the situation and to follow the rules of 6th article of Pharmacy Practice Act: who will take the medicine, which are the symptoms, how long are they lasting for, co-existing treatment and diseases and try to anticipate possible contraindications. (2, 6) The provided information is frequently scarce when visitors come to a pharmacy in the role of a courier, especially when the person in need is not their relative.

Pharmacists and pharmacy technicians provide counselling about dosing, application, potential adverse effects, and drug/drug- or drug/food-interactions, complemented by advice given on lifestyle and healthy living e.g., nutrition counselling and preventive care. (9) In cases when a visitor plays only a role of a courier, it is not possible to take into consideration all necessary information neither to explain everything and provide proper pharmaceutical care.

Should pharmacists dispense medicines even though they are not familiar with the patient's background?

There was a dilemma whether to dispense Dulcolax supp. for a visitor's neighbor. The visitor knew she is 72 years old and that she is diabetic. The visitor couldn't provide an answer to for how long the constipation is lasting, if the neighbor has a specific diet, which food does she eat, if she is exercising and how much, whether she is drinking enough, which medicines and supplements does she take or for how long is she helping herself with the medicine. (10)

Medical treatment with laxatives usually begins after the failure of diet and lifestyle modifications. Currently, there is a wide variety of therapeutic options. First-line treatment involves introducing bulk-forming and/or osmotic laxatives. If the patient is already taking either of these laxatives, changing or adding laxatives from these groups should be considered.

Keeping in mind that most patients that are seeking help for chronic constipation have potentially modifiable risk factors related to their lifestyle, the first response should not be a stimulant laxative. (7) The dilemma here is whether to dispense Dulcolax supp., as there is no information about her daily water intake, fibre-rich foods, level of exercise.

Pharmacist can explain proper use of medicine to the courier, however, the question is how much would the courier accept and the final user understand.

The stimulant laxative immediately relieves constipation problems. Problematic is long-term use, as it will eventually worsen the situation.

The safety of stimulant laxatives has been under close review by the MHRA for many years following concerns relating to misuse and abuse. (4) Chronic use or overdose may produce persistent diarrhea, hypokalemia and imbalance of other electrolytes, loss of essential nutritional factors, and dehydration. Prolonged use is not recommended as it may precipitate the onset of an atonic, non-functioning colon. Reported long-term side effects can also damage of renal tubules, metabolic alkalosis and muscle weakness. (5)

Communication is necessary in order to prevent harm from medicines (1) If no dialogue is being established people in need cannot have trust in community pharmacy and even don't recognize pharmacies as places where they can resolve their health-related problems. A part of pharmaceutical services is in that way missing. (8, 9)

If the community pharmacy accept the rule internally that they are not dispensing the wanted medicine when there is not enough information, people will go elsewhere or even search the drug via internet. If this practice is being followed, pharmacists cannot perform their job professionally and cannot help a patient as they should.

On the other hand, if the drug is dispensed with no understanding of the background, the situation will repeat and nobody pays attention. Pharmacists are not following the low and patient's health state can be worsening instead of improving.

In the community setting, pharmacists should be acknowledged as health-care professionals who patients can consult for health-related problems. (1) It is necessary to explain why we need information and to show others that coming to a pharmacy is beneficial for people's well-being. In order to do so, a proper communication must be established. (8)

For pharmacists to have an input into decisions, consultation is necessary. In order to act in the patient's best interest, pharmacist should get familiar with the background. Providing consumers with medicines alone is not sufficient to achieve the treatment goals. (10)

If there is no option for a face-to-face communication, at least telecommunication should be enabled. Another important feature that is missing here is follow up, since patients as well as pharmacists benefit from it. As pharmacists incorporate regular monitoring and follow-up of interventions and recommendations made in day-to-day practice, they will gain confidence and clinical experience that can be applied to other patients (8). The well-being of patients would improve when their issues are resolved and their quality of lives is not declining and is even improving.

Visitors should be strongly encouraged to be advised by a pharmacist regarding information they find elsewhere. (1)

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Each reference shall be marked with its own number.

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## FOOD SUPPLEMENTATION OR AN OFFICIALLY PRESCRIBED THERAPY?

IRMA-HERMINA KLEMENC

LEKARNA DRAVLJE

A 65-year old woman came in seek of advice to our pharmacy. She has already had a prescribed hypercholesterolaemia therapy with daily dose of 20 mg of rosuvastatin. Statins are especially known for possible cause of some side effects regarding muscle pain, tenderness or weakness, trouble lifting arms, trouble with standing, liver problems with upper stomach pain, tiredness, loss of appetite, dark urine, yellowing of the skin or eyes.(6)

As it happens, on her last visit to general physician's office, her blood test despite her current hypercholesterolaemia therapy, showed slightly high values of blood lipids. As a result, her physician advised her orally without a dosage regime to start treatment with Biostatine, food supplement containing lovastatin in the form of a red rice yeast. The letter was disused in European pharmaceutical industry due to frequent occurrence of previously mentioned side effects. However, she has already included physical activity into her everyday life. Through discussion about her diet, I advised her to rather include more fibre with whole grain wheats and unsaturated fats such as omega-3 found in fish and avocado into her daily meal choices.

National legislation of RS covers the administrative procedure of prescribing and dispensing practices of medicinal products in Rules on the classification, prescribing and dispensing of medicinal products for human use. Prescription is defined as an instruction written by a medical practitioner that authorizes a pharmacist to issue a medicine or treatment to the patient.

Medical practitioner by written prescription takes full responsibility for the patient's therapy. The need of effective public pharmacy service is defined in Pharmacy Practice Act (ZDL-1) along with prevention of wrongful medical treatments. According to valid pharmaceutical code of deontology, it is a moral duty of community pharmacists to provide wholesome healthcare service. Pharmacist's responsibility is to be fully aware of the patient's past and current treatments before he issues the prescribed treatment. Issued prescriptions are a legal proof of the medical practitioner's as well as pharmacist's actions.(1, 2)

Pharmacists in UK were first given prescribing rights for "supplementary prescribing" in 2003 following the successful completion of a supplementary prescribing course at a UK school of pharmacy and subsequent registration with their regulatory body. The supplementary prescribing is dependent on a prior diagnosis and an agreed and signed clinical management plan, developed in collaboration with the patient's general practitioner or hospital doctor. In the given case the independent prescriber (patient's general physician) still holds full responsibility for prescribed therapy. Once patient's medical therapy plan is in place, clinical responsibility and prescribing can be transferred to the supplementary prescriber from the doctor. In 2006, pharmacist prescribing rights in UK were extended to independent prescribing, allowing suitably qualified pharmacist to prescribe any medication for any diagnosed condition in collaboration with patient's general physician. This change gave pharmacist almost equal rights as independent medical prescribers, with shared moral clinical responsibility with patient's general physician for issued medication. According to one study from 2008, patient's views were positive, moreover, majority of responders were satisfied with their consultation with a prescribing pharmacist and with treatment advice they received from them. (3, 4, 5)

During our discussion about her starting an additional treatment with food supplement containing lovastatin, despite her existing prescribed therapy with rosuvastatin, I became immediately concerned about possible duplication of her hypercholesterolaemia therapy, to say the least. Not to mention, higher chances for occurrence of side effects known to be caused by statins, especially with dosage duplication of statins in the given case.(6)

Nevertheless, treatment with dietary supplement which in fact contains traces of active substance is dangerous because it's use is generally difficult to control since the dosage form is not designed for medicine accuracy. Her general physician should increase her daily dosage of rosuvastatin or consider possible change of her hypercholesterolaemia therapy and accordingly officially change her clinical management plan along with written prescription. In this way her medical practitioner would also take legal and moral responsibility for the change in her therapy. Be that as it may, by only informing her about complementing her existing hypercholesterolaemia therapy without any written documentation, her physician only hands his expert responsibility onto pharmacist. How should a pharmacist communicate this circumstances to a patient? How to prevent further non-documented physician's advices with a higher health impact?

Prescriptions are an official documentation of physician's diagnosis and his treatment choices. Medical practitioner has at his disposal a wider variety of diagnosis' options than any other healthcare professional. With written prescription medical practitioner takes legal and moral responsibility for prescribed treatment and authorizes a pharmacist to issue a medicine or treatment to the patient.

Nevertheless, if a pharmacist chooses to provide a patient with treatment in question only based on physician's informal information, any further consequences brought along by this additional treatment, would be a legal and moral responsibility of the pharmacist. However, when further complications of medical condition may occur, the consideration of food supplements in use is normally overlooked. Moreover, without any written documentation about patient's treatments whether with medical substances or food supplements, it is genuinely impossible to gain complete information about every substances in use, especially if time to react is short.

Medical practitioners are now more often than ever handing their expert responsibility onto other healthcare professionals, especially community pharmacists. However, pharmacists have the knowledge and experience to determine when self-medication is appropriate regarding potential interactions with prescribed conventional medications. Nevertheless, by doing so pharmacist also takes on responsibility for consequences for advised form of treatment. Moreover, Slovene chamber of pharmacy should reach an official arrangement with Medical chamber of Slovenia, so that all medical practitioners would accompany their advice about additional treatments with specific food supplements with written prescriptions. In this way, a formal documentation about every physician's choices of any form of treatment would exist.

According to professional code of deontology, it is in the best interest of the patients that community pharmacists along with general physicians take a stand about open ethical dilemmas. Moreover, community pharmacists should summarise all their daily moral and ethical inquiries to Slovene chamber of pharmacy. Committee for pharmaceutical deontology of Slovene chamber of pharmacy should gather and discuss all common and pressing moral issues. Furthermore, Slovene chamber of pharmacy should accommodate with Medical chamber of Slovenia about explications of compelling moral dilemmas and together announce their position publicly. This is a unique solution to maintain and reimburse moral integrity of pharmaceutical profession.

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Each reference shall be marked with its own number.

(e.g. 1: Source 1, 2: Source 2):

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