UST-40 version 1 Recommending Guideline on the Term "Expert"

This Guideline supersedes Guideline UST-40 as of 01 November 2023.

The Guideline is based upon legislative conditions stipulated by:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter referred to as the "MDR")
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (hereinafter referred to as the "IVDR")
- Act No 40/1995 Coll., on Advertising Regulation and on Amendments to Act No 468/1991 Coll., on the Operation of Radio and Television Broadcasting, as amended (hereinafter referred to as "Act No 40/1995 Coll., on Advertising Regulation")
- Act No 375/2022 Coll., on Medical Devices and in Vitro Diagnostic Medical Devices (hereinafter referred to as "Act No 375/2022 Coll.")
- Act No 48/1997 Coll., on Public Health Insurance and on Amendments to Some Related Acts, as amended (hereinafter referred to as "Act No 48/1997 Coll., on Public Health Insurance")
- Act No 95/2004 Coll., on Requirements for Acquisition and Recognition of Expert Competence and Specialised Competence to Practise the Profession of a Physician, Dentist and Pharmacist, as amended (hereinafter referred to as "Act No 95/2004 Coll.")
- Act No 96/2004 Coll., on Requirements for Acquisition and Recognition of Competence for Pursuing Paramedical Professions and Activities Associated with the Provision of Health Care and on Amendment to Some Related Acts, as amended (hereinafter referred to as "Act No 96/2004 Coll., on Non-Medical Healthcare Professions")
- Decree No 55/2011 Coll., on the operation of healthcare professionals and other expert staff (hereinafter referred to as "Decree No 55/2011 Coll.")
- Decree No 77/2018 Coll., on the determination of particulars and specimen of some documentary evidence of education for accredited qualification courses, certified courses, and specialised education (hereinafter referred to as "Decree No 77/2018 Coll.")

This Guideline applies only to advertising for medical devices (hereinafter referred to as "MD(s)") and in vitro diagnostic medical devices (hereinafter referred to as "IVD(s)"), and explains the term "expert" as referred to under the provision of Section 2a of Act No 40/1995 Coll., on Advertising Regulation, falling within the powers of the State Institute for Drug Control (hereinafter referred to as the "Institute").

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The provision of Section 2a of Act No 40/1995 Coll., on Advertising Regulation for MDs and IVDs stipulates: "*Comparative advertising for medicinal products intended for administration to humans (hereinafter referred to as "human medicinal products"), healthcare services, medical devices or in vitro diagnostic medical devices is permissible providing it meets the conditions stipulated by the Civil Code, it targets persons authorised to prescribe or dispense such medicinal products, medical devices or in vitro diagnostic medical devices (hereinafter referred to as "experts") and/or provide such healthcare services."*

Relevant provisions: Section 2a of Act No 40/1995 Coll., on Advertising Regulation

The aforementioned implies that the "expert" is a person authorised to prescribe or dispense MDs and IVDs as per their acquired specialisation, both for physicians pursuant to Act No 95/2004 Coll., and for healthcare professionals with a specialised or specific expert competence pursuant to Act No 96/2004 Coll., on Non-Medical Healthcare Professions. A healthcare professional with a specialised or specific expert competence is a person who acquired the specialised competence or specific expert competence through the completion of specialised education in an accredited facility or through completion of a Master´s degree (university education) – see below. Furthermore, Act No 48/1997 Coll., on Public Health Insurance, also stipulates prescription restrictions for the prescribing of MDs and IVDs. In relation to the aforementioned, also advertising for MDs and IVDs pursuant to the provision of Section 5m of Act No 40/1995 Coll., on Advertising Regulation, is targeted at these experts.

For the purposes of Act No 375/2022 Coll., a **medical device** shall mean a medical device as referred to under Art. 2(1) of the MDR; accessories for medical devices as referred to under Art. 2(2) of the MDR, and a product referred to under Annex XVI to the MDR.

For the purposes of Act No 375/2022 Coll., an **in vitro diagnostic medical device** shall mean an in vitro diagnostic medical device referred to under Art. 2(2) of the IVDR or its accessories referred to under Art. 2(4) of the IVDR.

For the purposes of Act No 375/2022 Coll., a **device** shall mean a medical device and an in vitro diagnostic medical device. A device shall mean a medical device, accessory for medical device, and product referred to under Annex XVI of the MDR."

Relevant provisions: Section 2 of Act No 375/2022 Coll.

***"A medical device** means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- *in vitro providing information by means of examination of specimens derived from the human body, including organ, blood and tissue donations, which **does not achieve** its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.*

The following products shall also be deemed to be medical devices:

- *devices for the control or support of conception;*
- *products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) of the MDR and of those referred to in the first paragraph of this point."*

Relevant provisions: Art. 2(1) of the MDR

***"Accessory** for a medical device **(hereinafter referred to as "MD accessory")** - means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)."*

Relevant provisions: Art. 2(2) of the MDR

Product referred to under Annex XVI to the MDR **(hereinafter referred to as "product")** - **LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)**

1. "Contact lenses or other items intended to be introduced into or onto the eye.

2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.

3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.

4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

5. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.

6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain."

Relevant provisions: Annex XVI to the MDR

*"**In vitro diagnostic medical device (hereinafter referred to as "IVD")** means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used for the examination of specimens in vitro, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:*

- *concerning a physiological or pathological process or state;*
- *concerning congenital physical or mental impairments;*
- *concerning the predisposition to a medical condition or a disease;*
- *to determine the safety and compatibility with potential recipients;*
- *to predict treatment response or reactions;*
- *to define or monitoring therapeutic measures.*

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.

A receptacle of a vacuum or other type intended by the manufacturer solely for the primary storage and keeping of specimen derived from the human body for the purposes of in vitro diagnostic examination. Products for general laboratory use are not in vitro diagnostic medical devices as long as they are not, with respect to their qualities, intended by the manufacturer solely for in vitro diagnostic examination."

Relevant provisions: Article 2(2) of the IVDR,
Section 2(2) and 2(3) of Act No 375/2022 Coll.

I. DEVICE PRESCRIPTION:

Devices (MDs, MD accessories, products) are prescribed **during the provision of healthcare services by a medical doctor or by a dentist** (hereinafter referred to as the "physician") or by another **healthcare professional with specialised or special expert competence** pursuant to the Act on Non-Medical Healthcare Professions (hereinafter referred to as the "prescriber") on medical prescription, which is

a) an **order** for a specific patient issued following agreement with the patient **in electronic format** (hereinafter referred to as the "electronic order");

b) an **order** for a specific patient issued **in paper format** (hereinafter referred to as the "paper order"); or

c) a **request form** for devices to be used during the provision of healthcare services.

(3) **A device which may jeopardise the health or life of people even if used in compliance with its intended purpose, if not used under physician's supervision, may be dispensed on medical prescription issued by a physician** or veterinary doctor only. The list of such devices is stipulated by the provision of Section 8 of Decree No 377/2022 Coll.

(4) A device is also dispensed on electronic order or on paper order **in case the patient is entitled to its reimbursement pursuant to the act governing public health insurance**.

(5) The electronic or paper order may be used with the dispensing person within 30 days of its issue, unless specified otherwise by the prescriber, no later, however, than within one year.

(6) A paper order **may not bear** any symbols or elements restricting the readability of the completed data, data about other healthcare providers or dispensing persons **or any advertising statements**. A blank

paper order form must not be stamped with the stamp of the healthcare provider.

(7) A paper order shall show data identifying the prescriber, the patient for whom the prescribed device is intended, the prescribed device, specifying the number of packs of the prescribed device, and the health insurance company, if the device is to be reimbursed from the public health insurance system. An implementing legal regulation stipulates the exact scope and structure of data to be shown on a paper order.

(8) Where the reimbursement of a device prescribed on a paper order is preconditioned by approval by the concerned health insurance company,

a) the health insurance company shall make a note on the order reading "Approved by health insurance company" or "Not approved by health insurance company", the date of the decision, the decision file number, signature, and imprint of the stamp of the health insurance company;

b) on the basis of a written approval by the health insurance company, the prescriber shall make a note on the order reading "Approved by health insurance company", the date of the health insurance company's decision on approval of the reimbursement, and decision file number; or

c) on the basis of a written approval of repeat prescription by the health insurance company, the prescriber shall make a note on the order reading "Approved by health insurance company", the date of the health insurance company's decision on approval of the repeat reimbursement, and decision file number.

(9) The prescriber shall file the written approval or a document evidencing the written approval of the health insurance company referred to under paragraph (8)(b) or (c) to the patient's medical documentation no later than within five working days of its delivery.

(10) Where the reimbursement of a device prescribed on an electronic order is preconditioned by approval by the concerned health insurance company, the health insurance company shall confirm for the prescriber, via the ePrescription system, whether the conditions under which reimbursement of the prescribed device may be claimed have been met. The confirmation referred to under sentence one shall not be made for electronic orders for devices for which the health insurance company has already confirmed its consent with repeat reimbursement of the concerned device for the specific patient via the ePrescription system. The confirmation referred to under sentence one may also include the health insurance company´s requirement that upon dispensing, the patient be provided with a device other than the prescribed one within the circulatory system.

(11) Where a device the reimbursement of which is preconditioned by approval by the concerned health insurance company is concerned, and the prescriber is a doctor of the Prison Service of the Czech Republic, the order shall be sent by this doctor to the concerned health insurance company for confirmation.

(12) Where the prescriber, having regard to the patient's condition of health, or the health insurance company in its approval of the device reimbursement from public health insurance9) insist on dispensing the prescribed device, they shall make a note on the paper order reading "Replacement not allowed" or activate the "No replacement" flag on the electronic order.

Relevant provisions: Section 28 of Act No 375/2022 Coll.

Requirements governing the electronic order are specified under Annex 2 hereto.

II. DEVICE DISPENSING:

Conditions governing the dispensing of devices (MDs, MD accessories, products):

(1) Devices shall be dispensed on the basis of an electronic order or paper order. Dispensing shall include the provision of information necessary for the correct and safe use of the dispensed device.

(2) During dispensing on the basis of an electronic order, the dispensing individual must forthwith inform the central electronic order repository via the ePrescription system that the prescribed device has been dispensed.

(3) Devices may be dispensed by dispensing persons only. A dispensing person shall mean the provider of healthcare services of pharmaceutical care, an operator of an optician's outlet or a person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance. The person with whom the health insurance company has concluded a contract on

dispensing pursuant to the act governing public health insurance may only dispense a device for which the contract on dispensing has been concluded.

(4) A device, except for a risk class I medical device, may be dispensed in a pharmacy or in a dispensary of devices solely by

a) a pharmacist of the relevant expert competence;

b) a pharmaceutical assistant of the relevant expert competence; or

c) an orthotist-prosthetist qualified to perform the profession without expert supervision or an orthopaedic prosthetist where dispensing of an orthotic-prosthetic device is concerned.

(5) An eye-correction device may be dispensed in an optician's outlet only. Such device may be dispensed only by

a) an optometrist;

b) a licensed eye optician or licensed eye technician;

c) an eye optician or eye technician; or

d) an ophthalmologist.

Relevant provisions: Section 32 of Act No 375/2022 Coll.

Details on device mail-delivery, device replacement, and obligations of the device dispensing person are provided in Annex 3 hereto.

The aforementioned implies that:

Expert – a person authorised to prescribe or dispense the device (MD, MD accessory, product).

MDs, MD accessories, products may be prescribed by:

- physician,
- dentist,
- another healthcare professional with specialised or special expert competence pursuant to Act No 96/2004 Coll., on Non-Medical Healthcare Professions,

on medical prescription, which is:

- electronic order,
- paper order,
- request form for devices for use during the provision off healthcare services.

A device may **be dispensed** only by a dispensing person who is:

- a provider of healthcare services of pharmaceutical care,
- an operator of an optician's outlet, or
- a person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance. The person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance may dispense only such device for which the contract on dispensing has been concluded.

A device, except for a risk class I medical device, **may be dispensed** in a pharmacy or dispensary **only by**:

- a pharmacist of the relevant expert competence,
- a pharmaceutical assistant of the relevant expert competence,
- an orthotist-prosthetist qualified to perform the profession without expert supervision,
- an orthopaedic prosthetist where dispensing of an orthotic-prosthetic device is concerned.

An eye-correction device may be dispensed in an optician's outlet only. Such device may be dispensed only by:

- an optometrist,
- a licensed eye optician, or
- licensed eye technician, eye optician or eye technician, or
- an ophthalmologist.

Risk class I devices may be dispensed in a pharmacy or medical device dispensary a person who meets the aforementioned requirements for a dispensing person, who is:

- a provider of healthcare services of pharmaceutical care,
- an operator of an optician's outlet, or
- a person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance. The person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance may dispense only such device for which the contract on dispensing has been concluded.

The provision of information necessary for the proper and safe use of the dispensed device shall form part of the dispensing.

A device which may jeopardise the health or life of people even if used in compliance with its intended purpose, if not used under physician's supervision, may be dispensed on medical prescription issued by a physician.

Relevant provisions: Section 28(3) and Section 32(3), 32(4), and 32(5) of Act No 375/2022 Coll.

Executive summary:

Devices (MDs, IVDs, MD accessories, products) may be prescribed by:
• physician,
• dentist,
• another healthcare professional with specialised or special expert competence pursuant to the Act on Non-Medical Healthcare Professions
on medical prescription, which is:
• electronic order,
• paper order,
• request form for a MD for use during the provision of healthcare services.
Devices **may be dispensed** only by a dispensing person who is:
• a provider of healthcare services of pharmaceutical care,
• an operator of an optician's outlet, or
• a person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance. The person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance may dispense only such device for which the contract on dispensing has been concluded.
Devices (MDs, MD accessories, products), except for risk class I, **may be dispensed** in a pharmacy or MD dispensary **only by**:
• a pharmacist of the relevant expert competence,
• a pharmaceutical assistant of the relevant expert competence,
• an orthotist-prosthetist qualified to perform the profession without expert supervision,
• an orthopaedic prosthetist where dispensing of an orthotic-prosthetic device is concerned.
• An eye-correction device may be dispensed in an optician's outlet only. Such device may be dispensed only by an optometrist, a licensed eye optician or licensed eye technician, an eye optician or eye technician, or an ophthalmologist.
The provision of information necessary for the proper and safe use of the dispensed device shall form part of the dispensing.
Relevant provisions: Section 28(1) and Section 32(3), 32(4), and 32(5) of Act No 375/2022 Coll.

Who is another healthcare professional with specialised expert competence pursuant to Act No 96/2004 Coll., on Non-Medical Healthcare Professions?

A healthcare professional with specialised competence is a person who has gained specialised competence by the completion of specialised education in accredited facilities or by the completion of a Master´s degree (university education).

By the successful completion of specialised education with an attestation examination, the healthcare professional gains specialised competence to perform specialised activities of the respective healthcare profession.

Relevant provisions: Section 55(1) of Act No 96/2004 Coll., on Non-Medical Healthcare Professions

In compliance with the Act on Medical Devices and the Act on Public Health Insurance, a healthcare professional with specialised competence may prescribe medical devices without expert supervision and without indication within the scope of his/her specialised competence, except for those devices that may jeopardise the health or lives of people even if used in compliance with their intended purpose of use, if not used under physician's supervision pursuant to the act governing medical devices and in vitro diagnostic medical devices.

Relevant provisions: Part Four, Section 53a of Decree No 55/2011 Coll., on the operation of healthcare professionals and other expert staff

"Another expert professional gains expert competence to perform the healthcare profession by completion of specialised education or an accredited qualification course pursuant to Title V; the list of these healthcare professions is provided under Title II, Parts 1 and 2."

Relevant provisions: Section 44 of Act No 96/2004 Coll., on Non-Medical Healthcare Professions

"Specialised education of healthcare professionals referred to under Title II, Part 1 is set forth by Section 56. Specialised education of healthcare professionals referred to under Title II, Part 2 is set forth by Section 57."

Relevant provisions: Section 55(2) of Act No 96/2004 Coll. on Non-Medical Healthcare Professions

Who is a healthcare professional with special expert competence pursuant to Act No 96/2004 Coll., on Non-Medical Healthcare Professions?

By the completion of a certified course, healthcare professionals or other expert professionals gain special expert competence for a closely defined healthcare activities that deepen the gained expert or specialised competence. A certified course cannot replace the completion of expert or specialised competence to perform a healthcare profession. A healthcare professional without specialised competence in the relevant field of specialised education may carry out only individual activities of the healthcare professional with specialised competence for which he/she gained special expert competence by the completion of a certified course.

Relevant provisions: Section 61(1) of Act No 96/2004 Coll. on Non-Medical Healthcare Professions

By completion of a certified course, the person gains special expert competence for closely defined healthcare activities.

A certified course cannot replace the acquisition of expert or specialised competence to perform a healthcare profession.

Following successful completion of a certified course, the accredited facility shall issue a certificate of the acquired special expert competence to the course graduate.

Relevant provisions: METHODOLOGICAL GUIDELINE ON THE PREPARATION AND IMPLEMENTATION OF A CERTIFIED COURSE EDUCATION PROGRAMME Methodological Guideline CK (MoH Bulletin no 7/2023)

Special particulars of the specialisation diploma are as follows:

a) specification of the date of passing the attestation examination;

b) identification of the field of specialised competence;

c) identification of the specialist;

d) imprint of the stamp of the Ministry of Health; and

e) signature of the chair of the sectoral attestation commission and signature of the person acting on behalf of the authorised organisation through which the Ministry of Health grants the diploma.

Relevant provisions: Section 2(4) of Decree No 77/2018 Coll., on the determination of particulars and specimen of some documentary evidence of education for accredited qualification courses, certified courses, and specialised education; see document specimen https://www.zakonyprolidi.cz/disk/cs/file/2018/2018c039z0077p003u001.pdf https://www.mzcr.cz/specializacni-vzdelavani/

- Annex 4 hereto refers

Annexes:

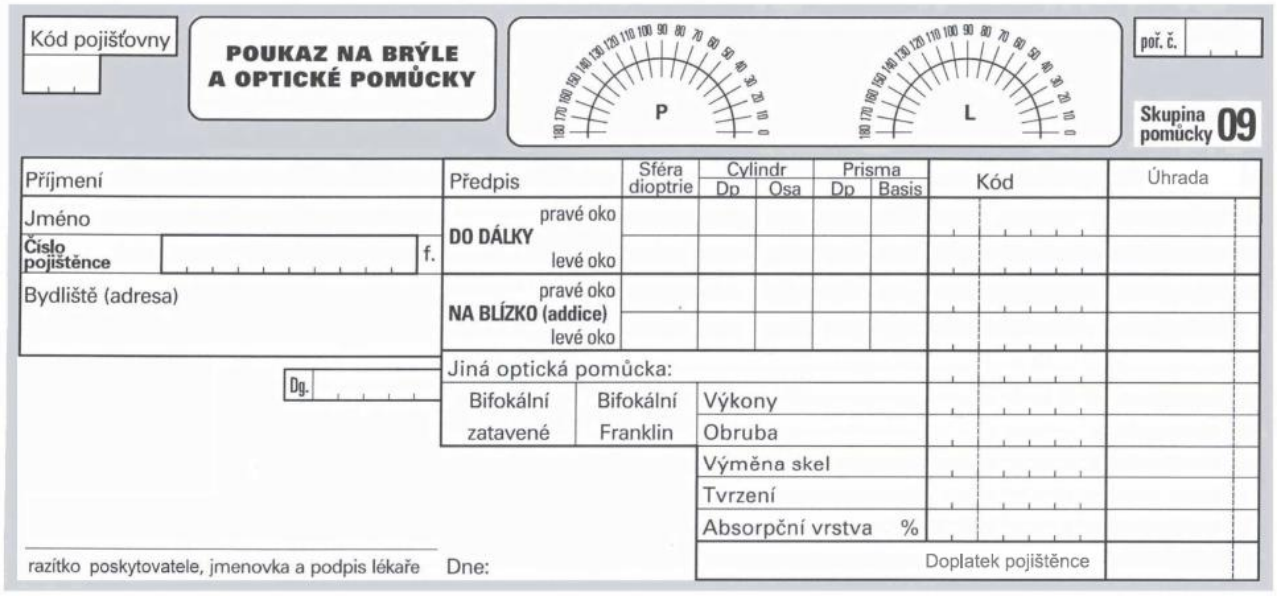
Annex 1 – Specimen paper orders for MDs

Annex 2 – Electronic order

Annex 3 – Device mail-delivery dispensing, device replacement, and obligations of the device dispensing person

Annex 4 – Specimen specialisation diploma

Annex 1 – Specimen paper orders for MDs:



Kód pojišťovny

POUKAZ NA BRÝLE A OPTICKÉ POMŮCKY

P L

poř. č.

Skupina pomůcky **09**

Příjmení	Předpis	Sféra dioptrie	Cylindr Dp	Cylindr Osa	Prisma Dp	Prisma Basis	Kód	Úhrada
Jméno	DO DÁLKY pravé oko							
Číslo pojištěnce f.	DO DÁLKY levé oko							
Bydliště (adresa)	NA BLÍZKO (addice) pravé oko							
	NA BLÍZKO (addice) levé oko							
Dg.	Jiná optická pomůcka:							
	Bifokální zatavené / Bifokální Franklin						Výkony	
							Obruba	
							Výměna skel	
							Tvrzení	
							Absorpční vrstva %	
							Doplatek pojištěnce	

razítko poskytovatele, jmenovka a podpis lékaře Dne:

Kód pojišťovny

POUKAZ NA LÉČEBNOU A ORTOPEDICKOU POMŮCKU

poř. č.

Příjmení a jméno

Číslo pojištěnce f.

Bydliště (adresa)

Vlastnictví pojišťovny: ANO/NE*)

Dg.

Stupeň postižení inkontinence:

Pomůcka trvalá / dočasná*)

*) nehodící se škrtněte!

Pomůcka dočasná na počet měsíců

Dne:

razítko poskytovatele, jmenovka a podpis lékaře

DRUH A OZNAČENÍ POMŮCKY

oprava – úprava pomůcky

Ev. č.

Pomůcka nová / repasovaná*)

*) nehodící se škrtněte!

Sk	Kód	Počet	Úhrada

Doplatek pojištěnce

Místo pro záznamy zdravotní pojišťovny

Datum uplatnění:

razítko výdejce

Kód pojišťovny

POUKAZ
NA FONIATRICKOU POMŮCKU

poř. č.

Skupina pomůcky **08**

Příjmení a jméno

Číslo pojištěnce f.

Bydliště (adresa)

Dg.

Dne:

razítko poskytovatele,
jmenovka a podpis lékaře

INDIKAČNÍ SKUPINA	Kód	Max. úhrada

ZNAČKA SLUCHADLA	Kód	Úhrada

PŘÍSLUŠENSTVÍ		
	Doplatek pojištěnce	

Datum uplatnění:

Prohlašuji, že

a) sluchadlo dostávám poprvé
b) naposledy jsem sluchadlo dostal(a) v roce .....

podpis

Potvrzuji, že mi bylo vydáno

a) sluchadlo
b) příslušenství ke sluchadlu

Nehodící se škrtněte!

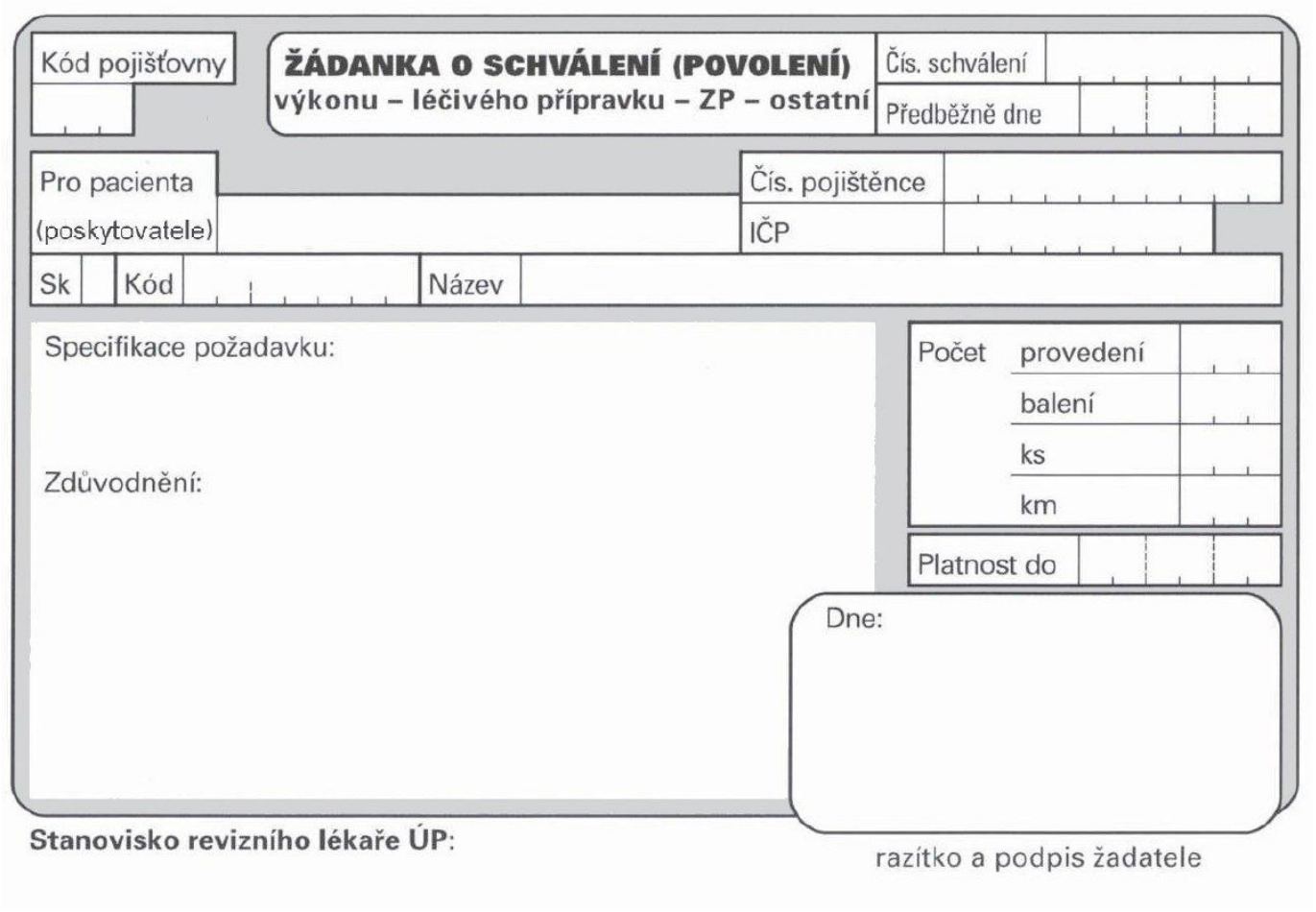
Dne:

podpis

VZP-14/2018

Místo pro záznamy zdravotní pojišťovny

Razítko výdejce


Kód pojišťovny
ŽÁDANKA O SCHVÁLENÍ (POVOLENÍ)
výkonu – léčivého přípravku – ZP – ostatní
Čís. schválení
Předběžně dne
Pro pacienta
(poskytovatele)
Čís. pojištěnce
IČP
Sk
Kód
Název
Specifikace požadavku:
Zdůvodnění:
Počet
provedení
balení
ks
km
Platnost do
Dne:
Stanovisko revizního lékaře ÚP:
razítko a podpis žadatele

Annex 2 – Electronic order:

Electronic order

(1) An electronic order is generated, changed or cancelled in the ePrescription system on the basis of a request of the prescriber, which contains data necessary for the generation, change or cancellation of the electronic order. The request for electronic order generation shall always contain information about the method of handing over the identifier of the electronic order (hereinafter referred to as "electronic order identifier") selected by the patient.

(2) In case of a device reimbursed from the public health insurance system, the prescriber's request for electronic order generation must always contain a numeric identifier of the prescribed device allocated thereto by the Institute pursuant to the Act on Public Health Insurance. A device that has not been allocated the numeric identifier referred to under sentence one, may be prescribed on electronic order by a physician only.

(3) In case the prescriber's request for electronic order generation contains all of the required data, the ePrescription system shall generate the electronic order and shall forthwith and without consideration inform the prescriber about the electronic order identifier borne by the electronic order. In case the patient requires that the electronic order identifier be sent thereto directly from the ePrescription system, the system shall provide it without consideration also to the patient.

(4) The identifier of the electronic order shall be provided to the patient without consideration; on electronic order hand-over, no specific healthcare provider may be preferred and the patient's right to select the dispensing person must not be hindered. Unless the patient chooses otherwise, the electronic order identifier shall be provided thereto by means of a paper form. The patient may choose to have the electronic order identifier sent thereto free of charge in a manner other than that mentioned in sentence two, specifically by

a) a data message sent to the patient's electronic mail address using the central electronic order repository service;
b) a text message sent to the patient's mobile phone device using the central electronic order repository service;
c) a data message using a web or mobile application of the ePrescription system made available by the Institute;
d) a data message sent on the basis of agreement with the prescriber to the patient's electronic mail address using the prescriber's information system service; or
e)) a text message sent on the basis of agreement with the prescriber to the mobile phone number of the patient's mobile phone device using the prescriber's information system service.

(5) **Regardless of the method of its hand-over, the electronic order identifier must not be accompanied by any statement of advertising nature**.

(6) The implementing legal regulation stipulates

a) the procedure and conditions for communication of prescribers and dispensing persons with the ePrescription system;
b) the form of electronic order identifier provided by the ePrescription system to prescribers and patients;
c) the method of submission of requests for generation, change, and cancellation of electronic orders by prescribers;
d) the scope of data necessary for the generation, change, and cancellation of electronic orders and particulars thereof;
e) the procedure and conditions for the communication of identification data referred to under Section 31(3)(b) and Section 31(4).

Relevant provisions: Section 29 of Act No 375/2022 Coll.

Central electronic order repository

(1) The Institute shall establish, administer, and operate a central electronic order repository as part of the ePrescription system. By means of the central repository of electronic prescriptions, the Institute safeguards the collection and storage of

a) electronic orders;

b) records on dispensing of devices on electronic order, including information about the actual device that was dispensed;

c) information concerning the handling of electronic orders.

(2) Via the ePrescription system, the Institute shall, without consideration, provide for the following:

a) immediate provision of the electronic order identifier to the prescriber and, where applicable, also to the patient upon request of the latter;

b) constant access for the dispensing person to the electronic order on the basis of which the prescribed device is to be dispensed;

c) constant access for the prescriber to electronic orders on which the prescriber prescribed devices;

d) constant access for the dispensing person to electronic orders on the basis of which devices were dispensed by this dispensing person;

e) access for the health insurance company to those electronic orders on which its insureds were dispensed devices reimbursed from public health insurance;

f) access for the Ministry to electronic orders on which devices were prescribed for persons whose healthcare services are paid for by the state.

(3) Via the ePrescription system, the Institute processes

a) the name(s), surname, date of birth, address of residence of the prescriber and his/her contact details and identification data of the healthcare provider, within the scope of whose operation the prescriber provides healthcare services, to the extent of its name, address of the healthcare facility, and site identification number, if allocated by the health insurance company;

b) the name(s), surname, date of birth, address of residence of the individual dispensing the device (hereinafter referred to as the "dispensing individual") and its contact details and identification data of the dispensing person to the extent of its name, address, and contact details;

c) identification data of the patients, to the extent of data provided on the medical prescription;

d) data about prescribed and dispensed devices, including the name, quantity, and numeric identification of the device, if allocated by the Institute.

(4) The Institute stores the information kept in the central electronic order repository, including data listed under paragraph (3), for the period of ten years of the expiry of the electronic order. After the expiry of this period, any information associated with such electronic order shall be removed from the ePrescription system.

Relevant provisions: Section 30 of Act No 375/2022 Coll.

Access to the central electronic order repository

1) The prescriber and the dispensing individual communicate with the central electronic order repository directly, via the ePrescription system, or via a communication interface of this system and the information system of the prescriber or dispensing individual.

(2) The physician who prescribes the device, and the pharmacist who dispenses the device in the provision of healthcare services in a pharmacy, shall access the ePrescription system in a manner specified by the Act on Pharmaceuticals.

(3)) A person other than the persons listed under paragraph (2) authorised to prescribe or dispense the device shall access the ePrescription system via an access certificate of the healthcare provider within the scope of which he/she provides healthcare services, of an operator of an optician’s outlet or a person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance; and

a) via the national Identification and Authentication Point;

b) by providing the identification data of this person by the healthcare provider within the scope of which this person provides healthcare services, by the operator of an optician’s outlet or person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance; or

c) via access data for the ePrescription system allocated by the Institute pursuant to the Act on Pharmaceuticals.

(4) The person authorised to prescribe or dispense a device referred to under paragraph (3) shall, moreover, access the ePrescription system also via the National Identification and Authentication Point, if the healthcare provider within whose scope this person provides healthcare services, the operator of an optician's outlet or a person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing the public health insurance, has provided the Institute with the identification data of such person in advance and in situations concerning

a) the prescribing of a device in the provision of health care in the patient's own social environment; or

b) the dispensing of a device in an optician's outlet or at a person's with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing the public health insurance.

(5) The information systems used by the prescriber for the purposes of prescribing and by the dispensing individual for the purposes of dispensing of devices must be fully compatible with the ePrescription system and compliant with its operating documentation.

(6) Data available to prescribers and dispensing individuals via the ePrescription system may be used solely for the purposes of prescribing and dispensing of devices.

(7) The implementing legal regulation stipulates:

a) the procedure and conditions for the provision of identification data as per paragraph (3)(b); and

b) the method of providing the identification data referred to under paragraph (4).

Relevant provisions: Section 31 of Act No 375/2022 Coll.

Annex 3 - Device mail-delivery dispensing, device replacement, and obligations of the device dispensing person:

Device mail-delivery dispensing

(1) Mail-delivery dispensing shall mean dispensing of a device on the basis of a paper or electronic order by mail delivery. The offering of devices for the purposes of mail-delivery dispensing and the receipt of orders from persons for the conduct of mail-delivery dispensing is considered part of mail-delivery dispensing. Mail-delivery dispensing must meet the requirements governing sale via information society services stipulated by the Medical Device Regulation or by the In Vitro Diagnostic Medical Device Regulation. Article 6 of the MDR Stipulates: "*Distance sales*

> *1. A device offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to a natural or legal person established in the Union shall comply with this Regulation.*
>
> *2. Without prejudice to national law regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535 or by other means of communication, directly or through intermediaries, to a natural or legal person established in the Union shall comply with this Regulation.*
>
> *3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.*
>
> *4. A Member State may, on grounds of protection of public health, require a provider of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to cease its activity."*

Article 6 of the IVDR stipulates: "*Distance sales*

> *1. A device offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to a natural or legal person established in the Union shall comply with this Regulation.*
>
> *2. Without prejudice to national law regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, or by other means of communication, directly or through intermediaries, to a natural or legal person established in the Union shall comply with this Regulation.*
>
> *3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.*
>
> *4. A Member State may, on grounds of protection of public health, require a provider of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to cease its activity*."

(2) Where devices referred to under Section 28(3) are concerned, mail-delivery dispensing is prohibited.

Relevant provisions: Section 33 of Act No 375/2022 Coll.

Groups of devices that may jeopardise the health or lives of people even if used in compliance with their intended purpose, if not used under physician's supervision, and which are dispensed on medical prescription only, are:

- intrauterine devices,
- devices to treat breathing disorders in sleep,
- implantable devices applied by injection,
- hearing aids, and
- contact lenses if used in children under the age of 15 years.

Relevant provisions: Section 8 of Decree No 377/2022 Coll.

Obligations of the person providing for mail-delivery dispensing of devices

In mail-delivery dispensing of devices, the dispensing person is obliged to

a) arrange for the publication of information about mail-delivery dispensing, offer of the device, its price, the timeline within which it is possible to send the device to the ordering party, and the costs associated with mail-delivery dispensing on its website; a mere publication of the offer shall not be considered advertising pursuant to the act governing advertising regulation;

b) make sure that the individual conducting the dispensing of the device meets the requirements set forth by Section 32(4) and (5);

c) provide for packaging and transportation; the dispensing person shall be responsible for maintaining the quality of the devices, even in cases where it contracts transportation of the device with another person;

d) make sure that the shipments are sent to the ordering party no later than within the timeline published as per letter (a) or that the ordering party is forthwith informed by the dispensing person about reasons for which delivery cannot be carried out or that it will be carried out at a later delivery date, including information about the duration of such delivery period; and

e) arrange for an information service provided by the dispensing person pursuant to Section 32(3) or by the authorised person pursuant to Section 32(4) and (5) during defined working hours; this information service shall also serve for the collection and hand-over of information about arising incidents.

Relevant provisions: Section 34 of Act No 375/2022 Coll.

Section 32(4) of Act No 48/1997 Coll., on Public Health Insurance stipulates: "***A provider authorised to dispense*** *medicinal products or* ***medical devices and contracted dispensing person must not in association with the dispensing*** *of the medicinal product or* ***medical device reimbursed from health insurance provide, offer or promise monetary or non-monetary credits or benefits or gifts of material or non-material nature, not even via third parties****; this shall not prejudice the possibility to provide a discount or final price reduction by not applying the maximum trade margin in the dispensing of such medicinal product or medical device."* The aforementioned implies that announcing free delivery of a medical device dispensed via mail-dispensing in the form of an advertisement could be considered a breach of this provision.

Device replacement

(1) During dispensing of a device prescribed on electronic or paper order, the dispensing person shall inform the patient about possible alternatives thereto and, upon the patient's consent, may replace it with another device which is replaceable with the prescribed device in terms of performance and intended purpose. The dispensing individual shall note the replacement made on the order.

(2) Where the paper order bears the note "Replacement not allowed" or the electronic order has an active "No replacement" flag, the dispensing person may dispense only the prescribed device.

Relevant provisions: Section 35 of Act No 375/2022 Coll.

Order excerpt

Where the dispensing individual does not have the full quantity of the device required by the prescription at the time of dispensing the device on paper order, he/she shall issue an excerpt of the order for the missing device which shall bear the word "Excerpt". The excerpt of the paper order shall contain data from the original paper order and information on the scope of the previously completed dispensing. The original paper order shall be marked with the words "Excerpt made" and with information on the scope of the completed dispensing. The period for which the excerpt of the paper order may be used shall be governed by Section 28(5) analogously.

Relevant provisions: Section 36 of Act No 375/2022 Coll.

Obligations of device dispensing persons

The dispensing person shall be obliged to

a) observe good storage practice;

b) provide the patient with the complete information about facts that may affect the patient's safety and health in association with the use of the device being dispensed;

c) store all paper orders and request forms for dispensed devices referred to under Section 28(3) for the period of five years, unless the device was reimbursed from public health insurance;

d) take out devices that cannot be used pursuant to Section 38(1) and store them separately.

Relevant provisions: Section 37 of Act No 375/2022 Coll.

Annex 4 – Specimen specialisation diploma:

Vzor diplomu o specializaci

MINISTERSTVO ZDRAVOTNICTVÍ ČESKÉ REPUBLIKY
Palackého nám. 4, 128 01 Praha 2, IČO: 00024341

Číslo diplomu:

DIPLOM
O SPECIALIZACI

Titul, jméno, příjmení

Datum a místo narození

dne získal(a) v souladu s ustanovením § 53 a § 54 zákona č. 96/2004 Sb., *o podmínkách získávání a uznávání způsobilosti k výkonu nelékařských zdravotnických povolání a k výkonu činností souvisejících s poskytováním zdravotní péče a o změně některých souvisejících zákonů* (zákon o nelékařských zdravotnických povoláních), ve znění pozdějších předpisů, vykonáním atestační zkoušky

specializovanou způsobilost

v oboru

s označením specialisty

podle nařízení vlády č. 31/2010 Sb., o oborech specializačního vzdělávání a označení odbornosti zdravotnických pracovníků se specializovanou způsobilostí.

L. S.

Titul, jméno, příjmení
Předseda oborové atestační komise

Titul, jméno, příjmení
Osoba jednající za pověřenou organizaci

Titul, jméno, příjmení
Osoba jednající za Ministerstvo zdravotnictví České republiky

V ..... *dne* .....