DOBRA PRAKSA U DISTRIBUCIJI LEKOVA DEO 1 i DEO 2- sličnosti i razlike

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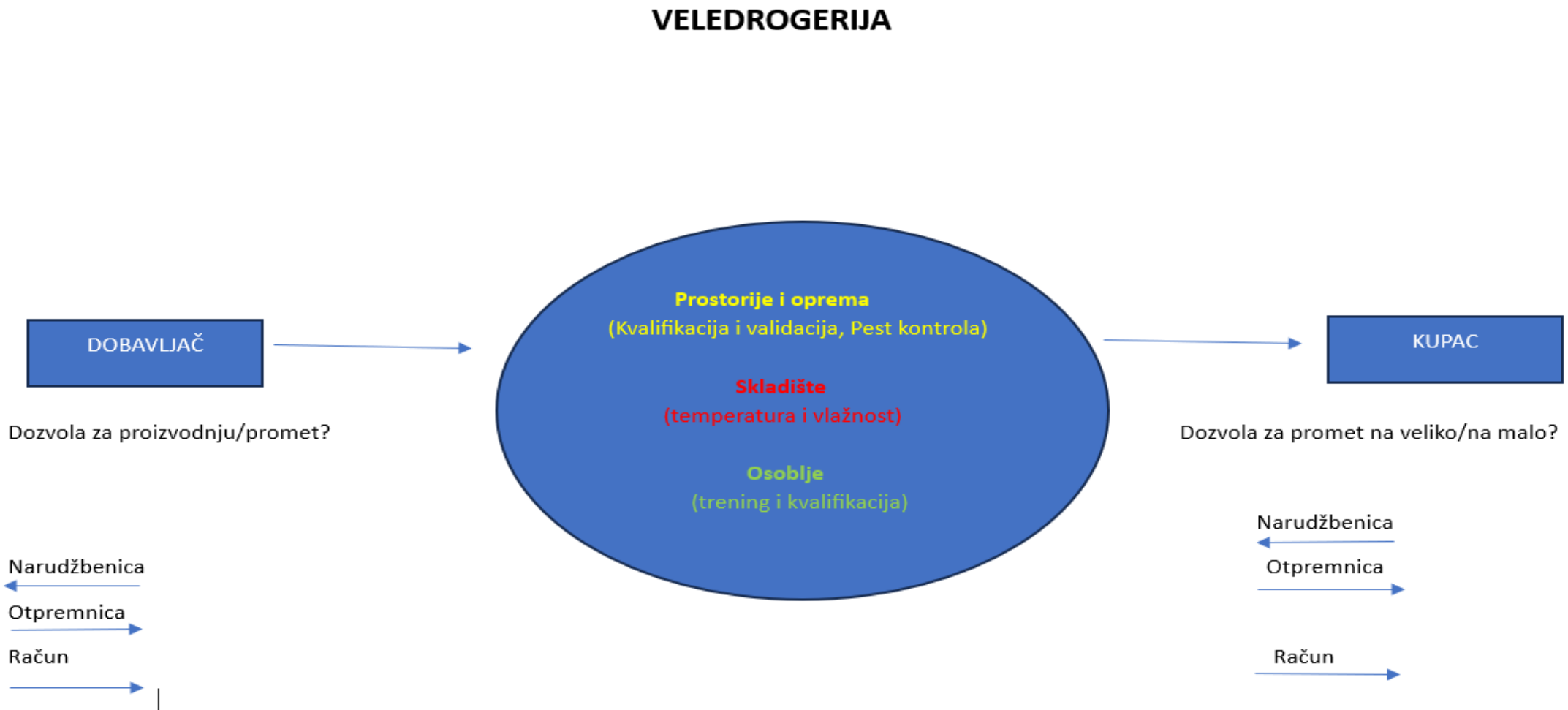
PRIVREDNA KOMORA SRBIJE 1857

SADRŽAJ

- Osnovni pricipi prometa na veliko
- Relevantni zakonski propisi
- Specifičnosti u distribuciji API
- Specifičnosti u distribuciji lekova
- Najčešća pitanja inspekcije i auditora

Osnovni pricipi prometa na veliko



Osnovni pricipi prometa na veliko

Relevantni zakonski propisi

EU

DIRECTIVE 2001/83/EC

- Definition of Wholesale
- Art. 76 -85

Guidelines on *Good Distribution Practice* of Medicinal Products for Human Use (2013/C 68/01**)**

SRBIJA

Pravilnik o uslovima za promet na veliko lekova i medicinskih sredstava, podacima koji se upisuju u Registar izdatih dozvola za promet na veliko lekova i medicinskih sredstava, kao i načinu upisa
"Službeni glasnik RS", br. 10/2012 i 17/2017

PRAVILNIK o dokumentaciji i načinu uvoza lekova koji nemaju dozvolu za lek, odnosno medicinskih sredstava koja nisu upisana u Registar medicinskih sredstava

"Službeni glasnik RS", br. 2 od 10. januara 2014, 14 od 7. februara 2014 - ispravka, 111 od 15. oktobra 2014, 52 od 17. juna 2015, 39 od 25. maja 2018 - dr. pravilnik, 75 od 6. septembra 2023.

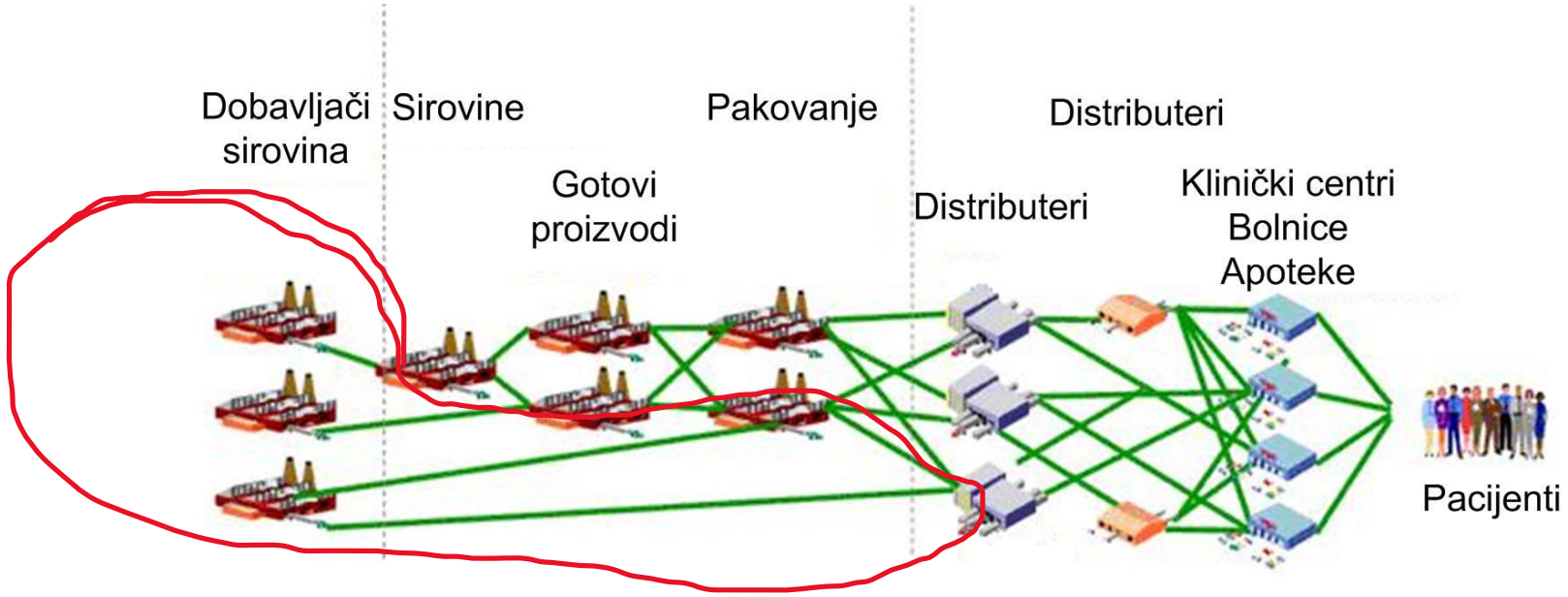
SMERNICE DOBRE PRAKSE U DISTRIBUCIJI (Sl. glasnik RS br. 13/16 , 44/16)

PRVI DEO SMERNICE DOBRE PRAKSE U DISTRIBUCIJI HUMANIH LEKOVA

DRUGI DEO - SMERNICE DOBRE PRAKSE U DISTRIBUCIJI AKTIVNIH SUPSTANCI ZA HUMANE LEKOVE

Farmaceutski lanac snabdevanja

- **Upravljanje snabdevanjem lekova** je proces strateškog planiranja, selekcije, nabavke, skladištenja, transporta i isporuke lekova u cilju obezbeđenja potreba zdravstvenih ustanova i pacijenta**.** Pacijent mora da dobije kvalitetan, bezbedan i efikasan lek u pravo vreme i na pravom mestu.



NABAVKA POLAZNIH MATERIJALA | PROIZVODNJA LEKOVA | DISTRIBUCIJA LEKOVA | IZDAVANJE LEKOVA

Pregled smernice

	GDP Part 1	GDP Part 2
1.	Upravljanje kvalitetom	Područje primene
2.	Osoblje	Sistem kvaliteta
3.	Prostor i oprema	Osoblje
4.	Dokumentacija	Dokumentacija
5.	Operativni postupci	Prostor i oprema
6.	Reklamacije, povraćaj, falsifikati i povlačenje	Operativni postupci
7.	Upravljanje poverenim aktivnostima (autsors)	Povraćaji, reklamacije i povlačenje iz prometa
8.	Interne provere	Interne provere
9.	Transport	
10.	Posrednici	-

Specifičnosti u distribuciji API

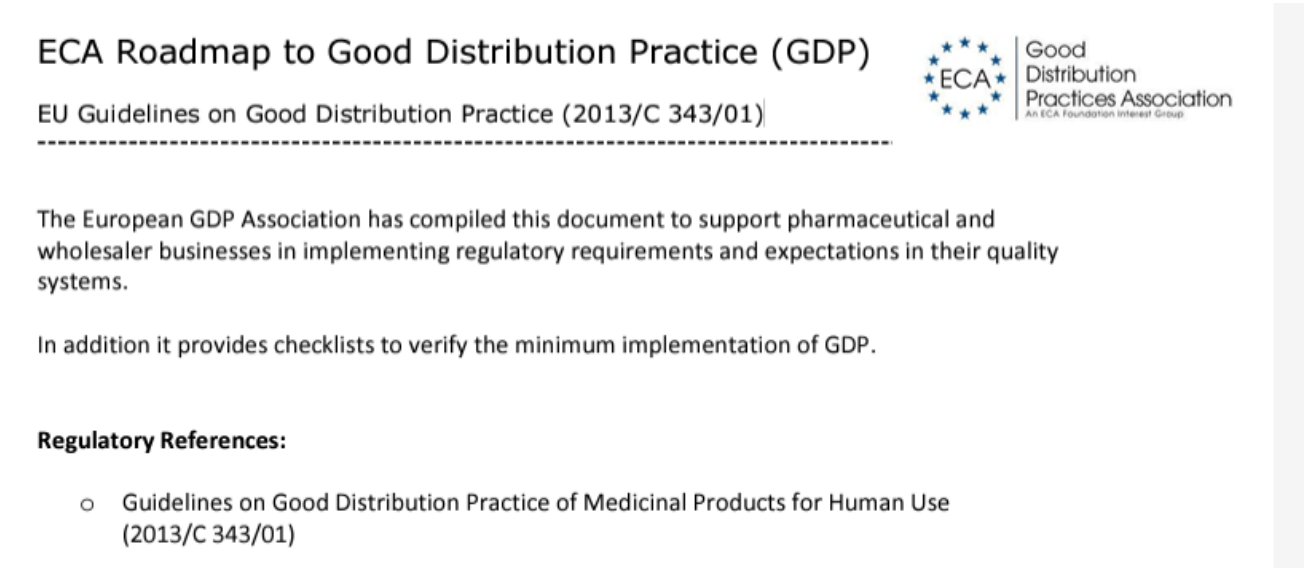
GDP Part 2	OPIS
Područje primene	Ne odnosi se na posredovanje u nabavci i uvozu Ne odnosi se na intermedijere
Sistem kvaliteta	Upravljanje rizicima, odstupanja, CAPA, Dobra dokumentaciona praksa, evaluacija
Osoblje	Odgovorno lice Obuka zaposlenih
Dokumentacija	Procedure i evidencije
Prostor i oprema	Pogodnost primene (psihoaktivne supstance) Pristup skladištu Kalibracija
Operativni postupci	Nabavka, prijem, skladištenje, isporuka kupcima, prenos informacija
Povraćaji, reklamacije i povlačenje iz prometa	Povraćaj; reklamacije i povlačenja
Interne provere	Planiranje, sprovođenje i evidencija internih provera

Zajedničke karakteristike

POGLAVLJE	AKTIVNOSTI
1. Upravljanje kvalitetom	QS, ChC, Mngm Rev, RM, Devijacije, CAPA
2. Osoblje	Ključno osoblje, RP, Obuka, higijena
3. Prostor i oprema	Prostorije, oprema,validacija i kvalifikacija, kalibracija, praćenje ambijentalnih uslova
4. Dokumentacija	Upravljanje dokumentacijom
5. Operativni postupci	Kvalifikacija dobavljača, kvalifikacija kupaca, prijem lekova,skladištene, farm. otpad, isporuka, nabavka/uvoz, izvoz
6. Reklamacije, povraćaj, falsifikati i povlačenje iz prometa	Reklamacije kupaca, povraćaj, sumnja na falsifikate, povlačenje iz prometa
7. Upravljanje poverenim aktivnostima (autsors)	Davalac ugovora, Primalac ugovora
8. Interne provere	Samoinspekcija
9. Transport	Uslovi, posebni uslovi transporta
10.Posrednici	Odgovornosti onih koji učestvuju u FLS, a nemaju fizičkog kontakta sa robom

Najčešća pitanja inspekcije i auditora

- Kontrolne liste Ministarstva zdravlja
- Kontrolne liste ECA



ECA Roadmap to Good Distribution Practice (GDP)

EU Guidelines on Good Distribution Practice (2013/C 343/01)

ECA Good Distribution Practices Association
An ECA Foundation Interest Group

The European GDP Association has compiled this document to support pharmaceutical and wholesaler businesses in implementing regulatory requirements and expectations in their quality systems.

In addition it provides checklists to verify the minimum implementation of GDP.

Regulatory References:

- Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01)

chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.good-distribution-practice-group.org/download/Roadmap-to-Good-Distribution-Practice.pdf datum pristupa 16.11.2023.

Primeri iz prakse

Competent Authority of Austria issues new GDP Non-Compliance Report

The Austrian Medicines and Medical Devices Agency has entered a new GDP Non-Compliance Report into the EudraGMDP database. The authority writes that major deficiencies were detected in the quality systems of a wholesale distributor, also related to the lacking awareness of the Responsible Person. As a consequence, the Wholesale Distribution Authorisation (WDA) for human and veterinary medicinal products was withdrawn.

- http://eudragmdp.ema.europa.eu/inspections/view/gdp/viewGDPCertificate.xhtml, datum pristupa 16.11.2023.

Non Compliance Reports

From Date: 2023-08-16 (YYYY-MM-DD)*

To Date: 2023-11-16 (YYYY-MM-DD)*

Search

1 to 2 of 2 Total Records 1

Report Number	EudraGMDP Document Reference Number	WDA No./API Reg.No.	OMS Organisatio Identifier	OMS Location Identifier	Site Name	Site Address	City	Postcode	Country	Inspection End Date	Issue Date
sukls67268/20	28303	sukls86341/20	ORG-100016072	LOC-100064581	Pharmacorp CZ s.r.o.	Kulkova 4001/4, Zidenice	Brno	615 00	CZ (Czechia)	2023-10-23	2023-11-13
INS-484035-102397839	28105	484035	ORG-100041675	LOC-100068748	Az-Naturemed GmbH	Doblegg 36, Doblegg	Hitzendorf	8151	AT (Austria)	2023-10-03	2023-10-09

1 to 2 of 2 Total Records 1

STATEMENT OF NON-COMPLIANCE WITH GDP

Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GDP non-compliance at a wholesale distributor

Part 1

Issued following an inspection in accordance with Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of Austria confirms the following:

The wholesale distributor (WDA): Az-Naturemed GmbH
Authorisation number : 484035
Site address: Doblegg 36, Doblegg, Hitzendorf, Steiermark, 8151

OMS Identifiers: (ORG-100041675 / LOC-100068748)

Scope of certificate: Human medicinal products, Veterinary medicinal products

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2023-10-03, it is considered that **it does not comply with the Good Distribution Practice** requirements referred to in Article 84 of Directive 2001/83/EC.

Part 2

Wholesale distribution activity affected : All authorized activities

Part 3

1. Nature of non-compliance: ☐ AZ-naturemed GmbH is selling products, that are not covered by the authorisation (products with special requirements).

☐ AZ-naturemed GmbH is exporting medicinal products. Export is not covered by the authorisation.

☐ AZ-naturemed GmbH is buying medicinal products from companies outside the EEA, which is not covered by the authorisation. AZ-naturemed does not hold a authorisation to import medicinal products from third countries.

☐ AZ-naturemed GmbH does not comply with the Guideline on Good Distribution Practice of medicinal products for human use:
☐ 5.2 Qualification of suppliers: not in compliance with the Guideline
☐ 5.8 Supply: not in compliance with the Guideline
☐ 1.2 Quality System: An effective quality system is not maintained
☐ 2.2 Responsible Person (R.P.) : The R.P. doesn't have appropriate competence and experience as well as knowledge of GDP. The R. P. doesn't carry out her duties in such a way as to ensure that the distributor demonstrates GDP compliance.

2. Action taken/proposed by the NCA: Withdrawal of the Wholesale Distribution Authorisation

Najčešće neusaglašenosti

- Skladište ne odgovara nacrtu koji je u Dozvoli
- Nedostatak sledljivosti
- Neadekvatna istraga kod reklamacija i devijacija
- Nedostatak/ neadekvatna procena rizika

- Nedostatak / neadekvatna kvalifikacija prostora, sistema i opreme
- Neadekvatna kvalifikacija hladnog lanca
- Nedostatak Ugovora (o kvalitetu) sa dobavljačima usluga

PRIVREDNA KOMORA SRBIJE

1857

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