

## INSTRUCTION FOR COMPLETING EXCEL TABLE FOR IMPORT OF VETERINARY MEDICINES THAT DO NOT HAVE MARKETING AUTHORISATION

This instruction is used when preparing the documentation for issuance of import authorisation for medicines that do not have a marketing authorization, and in accordance with Rulebook on more detailed conditions for the issuance of import authorization for a medicine that does not have marketing authorisation ("Official Gazette of Montenegro" No 19/24 from 5 March 2024, 034/24 od 12.04.2024), available on the portal <u>www.cinmed.me</u> in the section Legislation/Medicines/Veterinary medicines. The instruction refers to completing the excel table with medicines to be imported.<sup>1</sup>

The manner of completing excel table is as follows:

From employees of the Institute you will receive via e-mail an Excel table with veterinary medicines that were imported in the previous period. The table already contains medicines sorted alphabetically.

The applicant shall enter the following data into the columns marked in yellow:

- Batch number (column L)
- Quantity (column M)

- Country/countries which approved the package of the medicine for the batch to be imported into Montenegro as an integral part of the Decision on the issuance of marketing authorisation (column Q);

- Country / countries in which the batch of the medicine to be imported into Montenegro is placed on the market (column R).

Note: Data on medicines in columns that are not marked in yellow must not be changed. Should you have any suggestions regarding the data on medicines in the table, please send them to: <u>uvozljekovi@cinmed.me</u>.

First you need to make sure you are not positioned in the first, purple row. To avoid this, position yourself on any part of the table that is not part of the purple row.

To find a specific medicine in the table, click **Find & Select**, then **Find**.



<sup>&</sup>lt;sup>1</sup> The instruction may also be applied to the export of immunological veterinary medicines which do not have marketing authorisation and which were previously imported into Montenegro, whereby the columns L and M are completed.

A window will open in which you need to type the name of the medicine (or part of it):

	A	в	С	D	E	F	G	н	I	J
1	Šifra lijeka	Verzija lijeka	ATC	INN	Naziv lijeka	Farmaceutski oblik	Količina farmaceutskog oblika u pakovanju	Jačina lijeka	Ukupna zapremina	Proizvođač
64	QP53AC12001	1	QP53AC12	ciflutrin	BAYOFLY® POUR - ON	Rastvor za lokalno nakapavanje na kožu	500	10 mg/ml	ml	KVP Pharma + Veterinar Produkte GmbH, Njemačka
65	QJ01MA90024	1	QJ01MA90	enrofloksacin	BAYTRIL® FLAVOUR 150MG	Tableta	20	150 mg	tbl	KVP Pharma + Veterinar Produkte GmbH, Njemačka
66	QJ01MA90020	1	QJ01MA90	enrofloksacin	BAYTRIL® FLAVOUR 50 MG	Tableta	Find and Replace	8		8 23
67	QJ01MA90030	1	QJ01MA90	enrofloksacin	BAYTRIL® 10%	Rastvor za injekciju	Fi <u>n</u> d what: e	nrofloksacin		Options >>
68	QJ01MA90018	1	QJ01MA90	enrofloksacin	BAYTRIL® 2.5%	Rastvor za injekciju		Find Al	Eind Next	t Close

After that, click **Find Next**, or **Enter** on the keyboard.

The system will position you on the medicine name you chose. If that is not a medicine of requested strength, form, or package, click again **Find Next** or **Enter** and find a requested medicine.

You can use filters to make it easier to find a medicine. For example, on the top of the table where the column **Proizvođač** is, click the arrow, choose a specific manufacturer and then click **OK**.

	Н		1	J				
	Jačina lijeka	~	Ukupna zapremina 🔻	Proizvođač				
	£↓ 100 mg/r ∡↓	<u>S</u> o S <u>o</u> So	rt A to Z rt Z to A r <u>t</u> by Color	Þ				
	100 mg/r	<u>C</u> l F <u>i</u> l Te	<u>C</u> lear Filter From "Proizvođač" Filter by Color →					
I	100 mg/ml + mg/ml 🗸	Se	Search					
	100 mg/ml + mg/ml		— Krka d.d., Slovenija — Krka d.d., Veterinar Produkte — Laboratorios Calier S.A., Španija — LABORATORIOS HIPRA S.A., Španij					
	100 mg/ml + mg/ml	•	Laboratorios Karizo S.A., Španija Laboratorios Ovejero S.A., Španija Laleham Healthcare Limited, Velika					
	100 mg/ml + mg/ml			OK Cancel				

In that case, the system will only offer you medicines by the chosen manufacturer.

E	F	G	Н	1	J	
Naziv lijeka 🗸	Farmaceutski oblik	Količina farmaceutskog oblika u pakovanju <mark>▼</mark>	Jačina lijeka 🔻	Ukupna zapremina	Proizvođač	
ADVANTAGE® ZA MALE MAČKE I KUNIĆE KUĆNE LJUBIMCE	Rastvor za lokalno nakapavanje na kožu	1,6	100 mg/ml	ml	KVP Pharma + Veterinar Produkte GmbH, Njemačka	
ADVANTAGE® ZA VELIKE MAČKE I KUNIĆE KUĆNE LJUBIMCE	Rastvor za lokalno nakapavanje na kožu	3,2	100 mg/ml	ml	KVP Pharma + Veterinar Produkte GmbH, Njemačka	
ADVANTIX®	Rastvor za lokalno nakapavanje na kožu	10	100 mg/ml + 500 mg/ml	ml	KVP Pharma + Veterinar Produkte GmbH, Njemačka	
ADVANTIX®	Rastvor za lokalno nakapavanje na kožu	16	100 mg/ml + 500 mg/ml	ml	KVP Pharma + Veterinar Produkte GmbH, Njemačka	

Once you have found a requested medicine, enter quantity (without decimal point).

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	Šitra lijeka	Verzija Sjeka	ATC	INN	Naziv ijeka	Farmaceutski oblik	Količina farmaceutskog oblika u pakovanju	Jačina lijeka	Ukupna zapremina	Proizvodač	Broj serije	Količina	JM pakovanja - šiha	JM pakovanja naziv	Ciljne vrste životinja
	QJ01MA30024	- 1	QJ01MA30	enroffoksacin	BAYTRU® FLAVOUR 150MG	Tableta	20	150 mg	19/	KVP Pharma + Veterinar Produkte GmbH, Njemačka		40			Pai

For every batch to be imported into Montenegro please complete the field **Država/države u kojima je pakovanje lijeka za seriju koja se planira uvesti u Crnu Goru odobreno kao sastavni dio registracionog Rješenja** with the data on the country/countries which approved the package of the medicine as the integral part of the Decision on the issuance of marketing authorisation.

For every batch to be imported into Montenegro please complete the field **Država/države u kojima je serija lijeka čiji se uvoz planira u Crnu Goru stavljena u promet** with the data on the country/countries in which the batch in question has been placed on the market.

When you have selected all medicines, position at the beginning of the table, find column **Quantity**, click the arrow and choose last option (**Blanks**). After that click **OK** and chosen medicines with quantities and prices will be selected, so you may check them again.

	K	L	M			
np.	Registrov an ▼	Broj serije	Količina 🔻			
A₂↓	Sort Smalle	st to Largest				
Ă↓	Sort Larges	t to Smallest				
	Sor <u>t</u> by Col	or	►			
$\overline{W}$	<u>C</u> lear Filter	From "Količina"				
	Filter by Co	lor	Þ			
	Number <u>F</u> ilf	ters	►.			
	Search		Q			
		ks				
		Cancel				

Save this newly created table by clicking File, and then Save As.



The completed excel table shall be sent to the Institute electronically, as part of the application for import/export of medicines, on a CD, or via e-mail address: <u>uvozljekovi@cinmed.me</u>, with a reference to the file number (from the confirmation of receipt of the application for the issuance of import authorisation).

If you cannot find a medicine in the table (it has not been imported before), you may enter the data on that medicine directly into the excel table, below already selected medicines. Please enter all the data on the medicine (ATC, INN, brand name, form, strength, package, etc.) <u>but do not enter the data in the column</u> <u>A – šifra lijeka</u>.

The information system of the Institute shall be kept up-to-date and excel table shall be sent to all stakeholders regularly via e-mail.

Should you have any questions regarding this matter, please sent an e-mail to <u>uvozljekovi@cinmed.me</u>, or call 020/310-280, Department for veterinary medicines.