

INSTRUCTION FOR USING EXCEL TABLE FOR IMPORT OF MEDICINES THAT DO NOT HAVE MARKETING AUTHORISATION

This instruction shall be used when preparing the documentation for issuance of import authorisation for medicines that do not have marketing authorisation¹, in accordance with the instruction Required documentation for import of medicines that do not have marketing authorisation and import/export of blood products and immunological products, available on the portal www.cinmed.me in the section Human medicines/Import and export of medicines. The instruction refers to completing the excel table with medicines to be imported¹.

Manner of completing a table is as follows:

You will receive an excel table with medicines that were previously imported via e-mail from employees of the Institute. Medicines in the table are sorted alphabetically. Data to be entered by the applicant are listed as follows:

- **Batch number** (column L);
- **Quantity** (column M);
- **Country/countries in which the medicine is authorized for marketing** (column P);
- **Country / countries in which the packaging of the medicine for the batch to be imported into Montenegro is approved as an integral part of the 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);
- **Specification for the batch planned to be imported into Montenegro is identical to the specification approved in EU countries (YES / NO)** (column S).

Above-mentioned data shall be entered in columns highlighted in yellow.

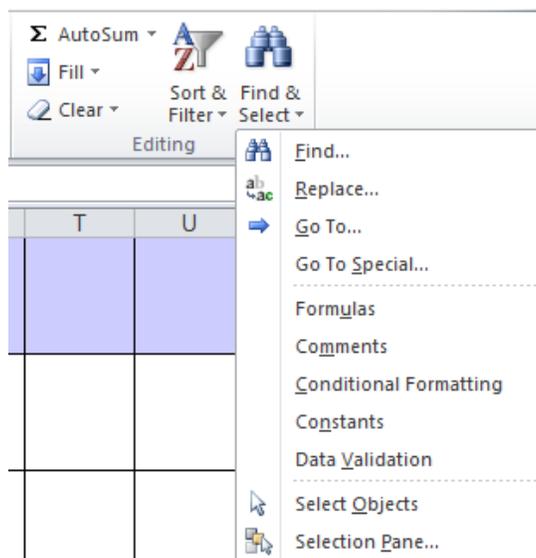
Note: Data on medicines in the columns that are not highlighted in yellow must not be changed. If you have any suggestions relating to data on medicines, please send them to: uvozlijekovi@cinmed.me

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

In order to find the specific medicine, click **Find & Select**, and then **Find**.

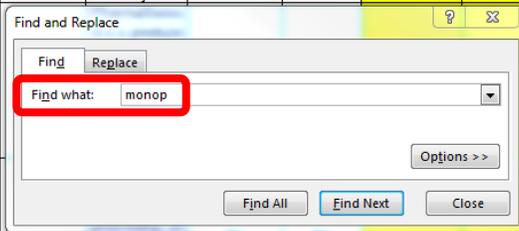
¹ The instruction can also be used when applying for the export of blood products and immunological products for human use, which do not have a marketing authorisation but were previously imported into Montenegro, whereby the columns L, M and P are completed.

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Then you type the name of the medicine (or part of it) in a window:

	A	B	C	D	E	F	G	H	I	J	K	L	M
1895	3544	C01DA14	izosorbid mononitrat	Monizol	Tableta	30	40mg		HEMOFARM A.D., Srbija	Da	Da		
	5487	J04AA01	aminosalicilna kiselina (PAS)	Monopas	Film tableta	30	500mg		MACLEODS PHARMACEU TICALS LIMITED, Indija	Ne	Ne		
1896	2847	C09AA09	fosinopril	Monopril	Tableta	28	20mg						
1897	2864	C09AA09	fosinopril	Monopril	Tableta	28	10mg						
1898	3937	C09BA09	fosinopril, hidrohloriazid	Monopril plus	Tableta	28	20mg + 12.5mg		PharmaSwiss d.o.o. preduze će za proizvodnju, un utrašnju, spoljn ju trgovinu i zastupanje, Srbija	Da	Da		
1899									PharmaSwiss d.o.o. preduze će za proizvodnju, un utrašnju, spoljn ju trgovinu i zastupanje, Srbija	Da	Da		

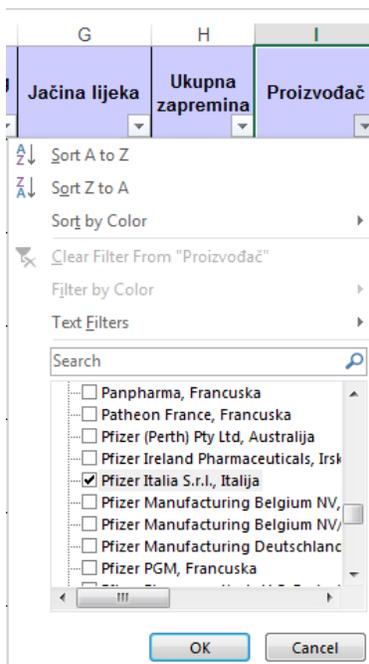


After that, click **Find Next** or **Enter**.

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

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You may also use filters, so you could find medicines more easily. For example, on the top of the table where column **Manufacturer** is, click the arrow, select required manufacturer and then click **OK**.

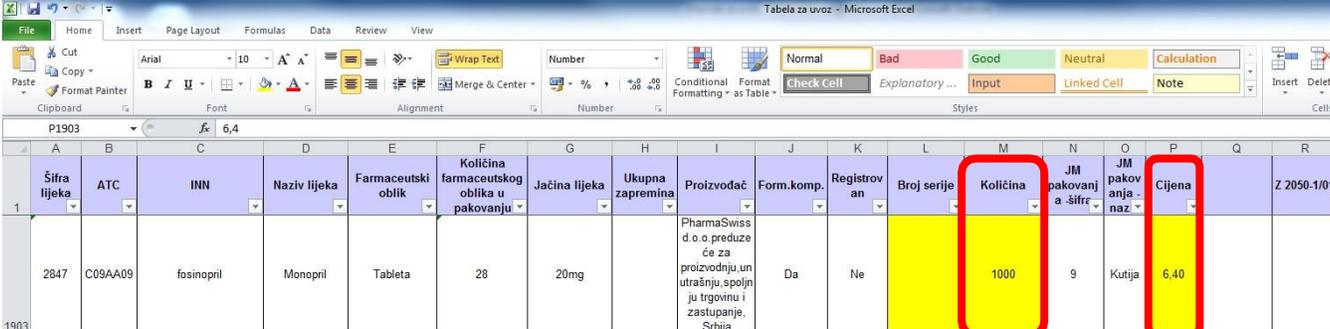


In that case, the system will offer you only medicines manufactured by a specific manufacturer.

F	G	H	I	J	K	L	M	N	O	P	Q	R
Količina farmaceutskog oblika u pakovanju	Jačina lijeka	Ukupna zapremina	Proizvođač	Form.komp.	Registrov an	Broj serije	Količina	JM pakovanja - šifre	JM pakovanja - naz	Cijena		Z 2050-1/01
30	25mg		Pfizer Italia S.r.l., Italija	Da	Da			9	Kutija			
28	2mg		Pfizer Italia S.r.l., Italija	Da	Da			9	Kutija			
28	1mg		Pfizer Italia S.r.l., Italija	Da	Da			9	Kutija			
8	0.5mg		Pfizer Italia S.r.l., Italija	Ne	Ne			9	Kutija			
100	140mg		Pfizer Italia S.r.l., Italija	Da	Da			9	Kutija			
30	4mg		Pfizer Italia S.r.l., Italija	Da	Ne			9	Kutija			

Once you have found the required medicine, enter batch number and quantity (without decimal point).

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Šifra lijeka	ATC	INN	Naziv lijeka	Farmaceutski oblik	Količina farmaceutskog oblika u pakovanju	Jačina lijeka	Ukupna zapremina	Proizvođač	Form.komp.	Registrovan	Broj serije	Količina	JM pakovanja - šifra	JM pakovanja - naziv	Cijena	Z 2050-1/01
2847	C09AA09	fosinopril	Monopril	Tableta	28	20mg		PharmaSwiss d.o.o. preduzeće za proizvodnju, unutrašnju, spoljnu trgovinu i zastupanje, Srbija	Da	Ne		1000	9	Kutija	6.40	

In the field **Country/countries in which the medicine is authorized for marketing**, provide the information on the country/countries (EU Member States, or countries that have the same or similar requirements as the EU Member States for issuance of marketing authorisation) where the medicine has been granted a marketing authorization.

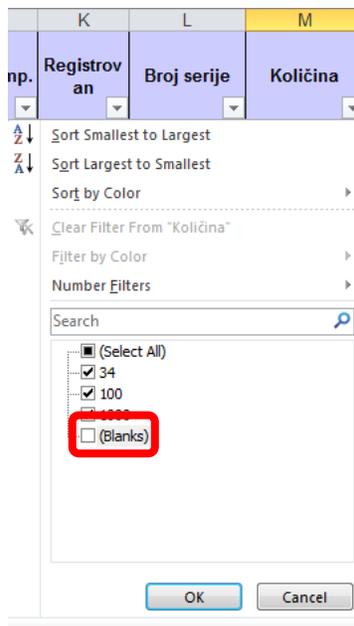
In the field **Country/countries in which the packaging of the medicine for the batch to be imported into Montenegro is approved as an integral part of the marketing authorisation** provide the information on the country/countries where the packaging of the medicine is approved as an integral part of the marketing authorisation for each batch that is planned to be imported in Montenegro,

In the field **Country/countries in which the batch of the medicine to be imported into Montenegro is placed on the market**, provide the information on the country/countries where the batch is placed on the market for each batch of the medicine that is planned to be imported into Montenegro.

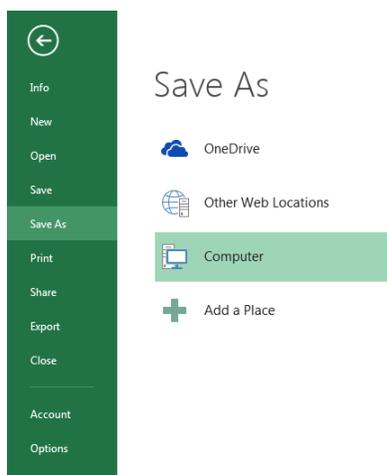
In the field **Specification for the batch planned to be imported into Montenegro is identical to the specification approved in EU countries (YES / NO)** provide the answer whether the specification is identical to the specification approved in EU Member States for each batch number planned to be imported into Montenegro.

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

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



Please send the completed excel table to the Institute electronically, as part of the documentation for import/export of medicines (on a CD or to the e-mail address: pisarnica@cinmed.me, along with the application, or via e-mail uvozljekovi@cinmed.me , with a reference to the file number).

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If required medicine cannot be found in the table (medicine was not previously imported), data on that medicine can be entered directly in the table, below already chosen medicines.

Enter all data on the medicine (ATC, INN, name of the medicine, dosage form, strength, packaging, etc.) **but do not enter the data in the column A - Code of a medicine.**

Information system of the Institute is kept up-to-date and updated excel table is sent periodically to all applicants via e-mail.

If you have any questions about finding a specific medicine, or completing a table, please send a question to: uvozljekovi@cinmed.me or call: 020/310-280, Department for Issuance of Import/Export Authorisation.