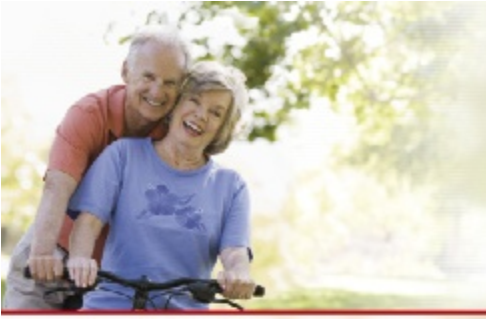
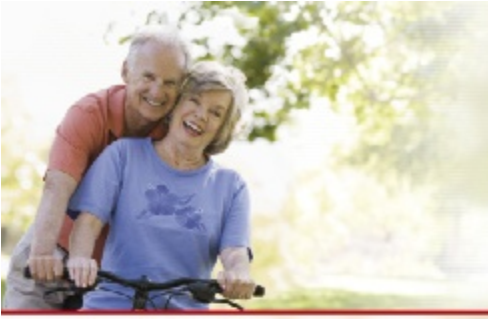


CML Association of Serbia

Fighting against Anzovip, a generic drug

CML Association of Serbia
Jelena Cugurovic

CML Horizons, Prague, May 2013.

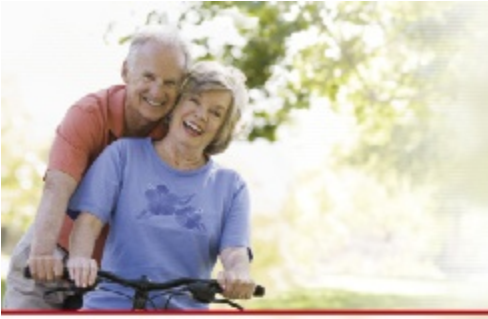


CML Serbia

- **Who are we?** CML Serbia is a nonprofit organization whose main goal is to help CML patients and their family members by providing them newest information about therapies, nutrition, ways of life, etc.

- **Who are our members?** CML patients, their family members and caregivers and friends of association. We have 175 patient members & 60 other members.

ASSOCIATION CML OF SERBIA



Situation Overview

How patients get their medications?

- In Serbia there are 5 referent centers in 5 cities.
- On the state level there is a republican committee which consists of hematologists from each referent center, who consider each patient individually. They decide on the therapy for each patient.

- **Republic Health Insurance Fond** is a state institution. Most people have state insurance and get their medications from RHIS. There are no private insurance funds.
- Health Insurance Fund decide which medication will be used (positive medication list) and they distribute the medications to referent centers.

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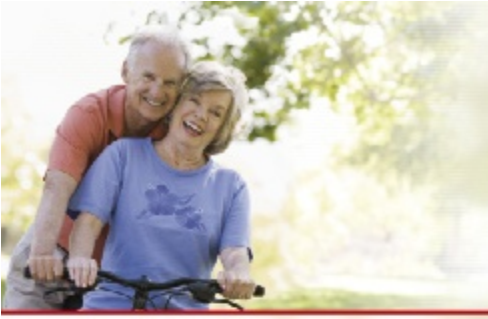
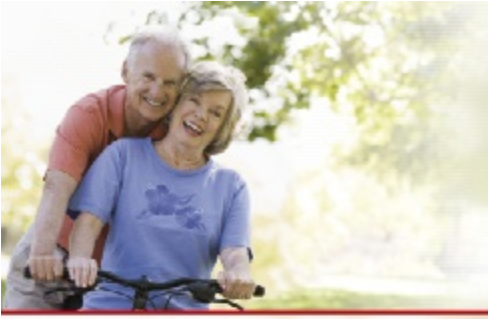


Situation Overview

- Drugs on the positive list in RHIF until July 2012:
  - Imatinib (Glivec) as a 1st line therapy
  - Nilotinib (Tasigna) as a 2nd line therapy
- 220 patients were on Glivec & 20 patients on Tasigna

- **In July 2012** using the ``fast`` procedure RHIF introduced the new imatinib drug called **Anzovip** on the positive list.
- All patients using Glivec were switched to Anzovip and all newly diagnosed patients started with Anzovip therapy.

- CML Serbia found out that Anzovip was introduced after the whole process of introduction was finished.



What is Anzovip?

- **Anzovip** (imatinib) is a new generic drug produced by Zdravlje Actavis.
- Data about its production is considered to be the secret by Zdravlje Actavis and Medical Agency in Serbia. We assume that it is produced in India and only repacked in Serbia.
- It is **4 times** cheaper than the original Glivec!
- Nobody (doctors, patients, …) knows anything about Anzovip.
- Serbia is the first country in Europe with the generic drug!

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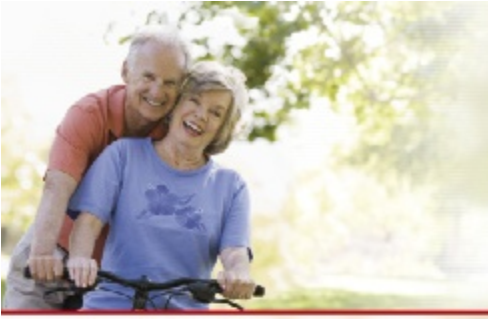

Our goals

- Immediately after we found out that Anzovip was introduced we started our campaign against it and set our goals.

- **MAIN GOALS are:**

1. Fighting against the generic drug – to remove Anzovip from the therapy and to bring back Glivec.
2. Increase number of patients who can get nilotinib (Tasigna) – easier transfer from imatinib to nilotinib.
3. Make nilotinib available as 1st line therapy.

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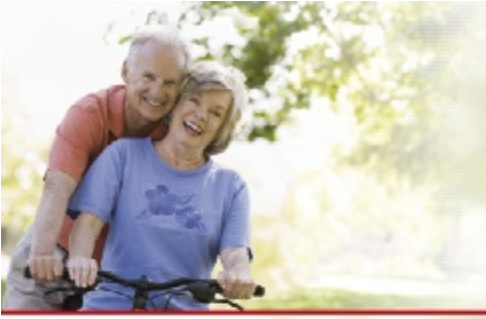
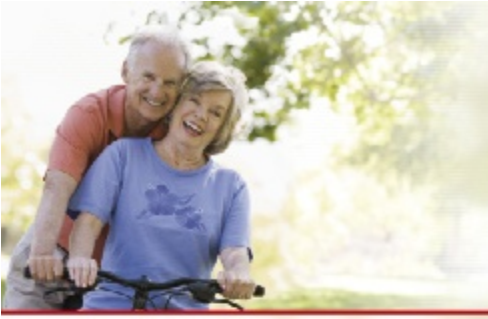


Our goals

- **SUPPORTING GOALS** according to the new situation:

4. Sending generic drug to independent testing in some laboratory in Europe by government officials – comparison testing of Anzovip & Glivec.
5. Arranging with hematologists to monitor patients more carefully and to have PCRs more often.



How did we fight?

- As soon as we found out we sent letters to RHIF, Ministry of Health and Deputy Prime Minister stating and asking **questions**:

- CML Serbia is not against generic drugs but against drugs which nobody knows anything about and which come from suspicious markets.

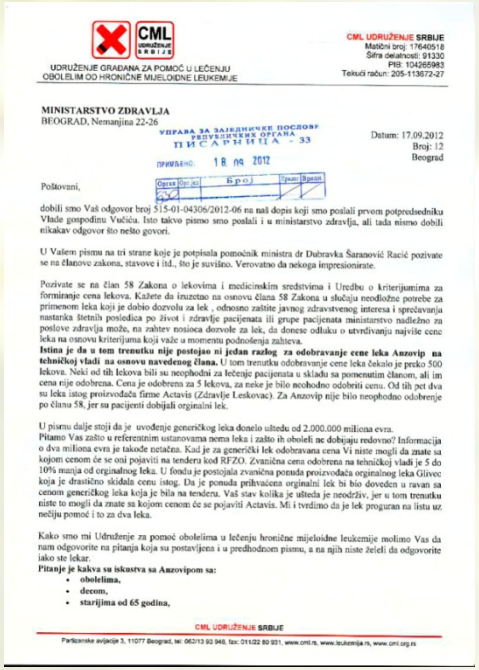
- Where is Anzovip produced, in which factory because there is no date about it? (We assume it is India.)

How did we fight?

- What are the experiences with treating patients with Anzovip?

- Where is bioequivalence study done and by whom? Is Anzovip registered in that country? Do patients take Anzovip in that country?

- What is the crystalline form of the drug? (λ or β? Glivec is β)



CML UDRUŽENJE SRBIJE
UDRUŽENJE GRAĐANA ZA POMOĆ U LEČENJU OBOLELIM OD HRONIČNE MIJELOIDNE LEUKEMIJE
Matični broj: 17640518
Šifra delatnosti: 91330
PIB: 104265983
Tekući račun: 205-113072-27

MINISTARSTVO ZDRAVLJA
BEOGRAD, Nemanjina 22-26

УПРАВА ЗА ЗАЈЕДНИЧКЕ ПОСЛОВЕ РЕПУБЛИЧКИХ ОРГАНА
ПИСАРНИЦА - 33
ПРИМЉЕНО: 18. 09. 2012

Datum: 17.09.2012
Broj:12
Beograd

Poštovani,

dobili smo Vaš odgovor broj 515-01-04306/2012-06 na naš dopis koji smo poslali prvom potpredsedniku Vlade gospodinu Vučiću. Isto takvo pismo smo poslali i u ministarstvo zdravlja, ali tada nismo dobili nikakav odgovor što nešto govori.

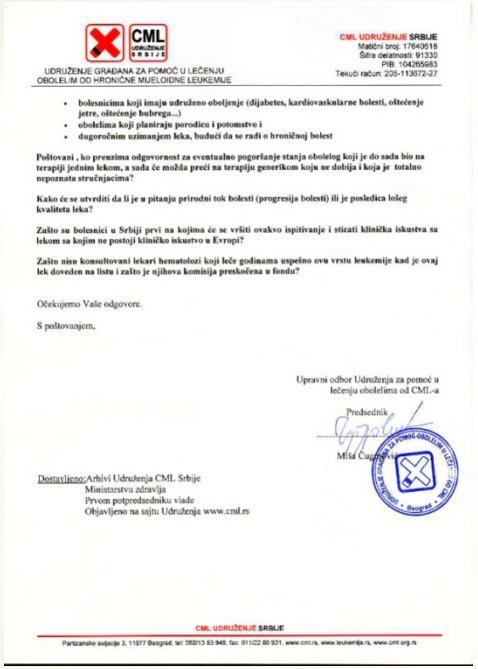
U Vašem pismu na tri strane koje je potpisala pomoćnik ministra dr Dubravka Šaranović Racić pozivate se na članove zakona, stavove i itd., što je suvišno. Verovatno da nekoga impresionirate.

Pozivate se na član 58 Zakona o lekovima i medicinskim sredstvima i Uredbu o kriterijumima za formiranje cena lekova. Kažete da izuzetno na osnovu člana 58 Zakona u slučaju neodložne potrebe za primenom leka koji je dobio dozvolu za lek , odnosno zaštite javnog zdravstvenog interesa i sprečavanja nastanka štetnih posledica po život i zdravlje pacijenata ili grupe pacijenata ministarstvo nadležno za poslove zdravlja može, na zahtev nosioca dozvole za lek, da donese odluku o utvrđivanju najviše cene leka na osnovu kriterijuma koji važe u momentu podnošenja zahteva.
Istina je da u tom trenutku nije postojao ni jedan razlog za odobravanje cene leka Anzovip na tehničkoj vladi na osnovu navedenog člana. U tom trenutku odobravanje cene leka čekalo je preko 500 lekova. Neki od tih lekova bili su neophodni za lečenje pacijenata u skladu sa pomenutim članom, ali im cena nije odobrena. Cena je odobrena za 5 lekova, za neke je bilo neohodno odobriti cenu. Od tih pet dva su leka istog proizvođača firme Actavis (Zdravlje Leskovac). Za Anzovip nije bilo neophodno odobrenje po članu 58, jer su pacijenti dobijali originalni lek.

U pismu dalje stoji da je uvođenje generičkog leka donelo uštedu od 2.000.000 miliona evra. Pitamo Vas zašto u referentnim ustanovama nema leka i zašto ih obolели ne dobijaju redovno? Informacija o dva miliona evra je takođe netačna. Kad je za generički lek odobravana cena Vi niste mogli da znate sa kojom cenom će se oni pojaviti na tenderu kod RFZO. Zvanična cena odobrena na tehničkoj vladi je 5 do 10% manja od orginalnog leka. U fondu je postojala zvanična ponuda proizvođača orginalnog leka Glivec koja je drastično skidala cenu istog. Da je ponuda prihvaćena originalni lek bi bio doveden u ravan sa cenom generičkog leka koja je bila na tenderu. Vaš stav koliko je ušteda je neodrživ, jer u tom trenutku niste to mogli da znate sa kojom cenom će se pojaviti Actavis. Mi i tvrdimo da je lek proguran na listu uz nečiju pomoć i to za dva leka.

Kako smo mi Udruženje za pomoć obolelima u lečenju hronične mijeloidne leukemije molimo Vas da nam odgovorite na pitanja koja su postavljena i u predhodnom pismu, a na njih niste želeli da odgovorite iako ste lekar.
Pitanje je kakva su iskustva sa Anzovipom sa:
- **obolelima,**
- **decom,**
- **starijima od 65 godina,**

CML UDRUŽENJE SRBIJE
Partizanske avijacije 3, 11077 Beograd, tel: 062/13 93 948, fax: 011/22 80 931, www.cml.rs, www.leukemija.rs, www.cml.org.rs



CML UDRUŽENJE SRBIJE
UDRUŽENJE GRAĐANA ZA POMOĆ U LEČENJU OBOLELIM OD HRONIČNE MIJELOIDNE LEUKEMIJE
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- **bolesnicima koji imaju udruženo oboljenje (dijabetes, kardiovaskularne bolesti, oštećenje jetre, oštećenje bubrega...)**
- **obolelima koji planiraju porodicu i potomstvo i**
- **dugoročnim uzimanjem leka, budući da se radi o hroničnoj bolest**

Poštovani , ko preuzima odgovornost za eventualno pogoršanje stanja obolelog koji je do sada bio na terapiji jednim lekom, a sada će možda preći na terapiju generikom koju ne dobija i koja je totalno nepoznata stručnjacima?

Kako će se utvrditi da li je u pitanju prirodni tok bolesti (progresija bolesti) ili je posledica lošeg kvaliteta leka?

Zašto su bolesnici u Srbiji prvi na kojima će se vršiti ovakvo ispitivanje i sticati klinička iskustva sa lekom sa kojim ne postoji klinička iskustva u Evropi?

Zašto nisu konsultovani lekari hematolozi koji leče godinama uspešno ovu vrstu leukemije kad je ovaj lek doveden na listu i zašto je njihova komisija preskočena u fondu?

Očekujemo Vaše odgovore.

S poštovanjem,

Upravni odbor Udruženja za pomoć u lečenju obolelima od CML-a

Predsednik

Miša Cu

Dostavljeno: Arhivi Udruženja CML Srbije
Ministarstva zdravlja
Prvom potpredsedniku vlade
Objavljeno na sajtu Udruženja www.cml.rs

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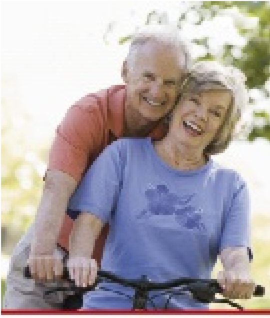


How did we fight?

- We did not get any concrete answers to any of our questions.

↓

- On 22.09. we asked the same questions and contacted the media to draw the public attention to the fact that CML patients in Serbia are the only one in the world who take the drug with unknown origin and unknown to professional public.

↓

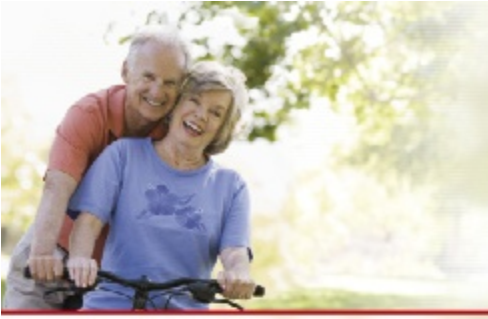
- We got the support from the most important and credible newspapers and web portals: Politika, Novosti, Danas, B92.

↓

Лек „анзовип” се тестира у Француској

За Удружење за помоћ у лечењу оболелих од ЦМЛ, генерички лек и даље мистериозан

Одбор за здравље: оболелу децу лечити „гливеком”



How did we fight?

↓

- Actavis, pharmaceutical company, started counter fight by writing PR texts against our campaign and the association: newspaper Blic and Informer.

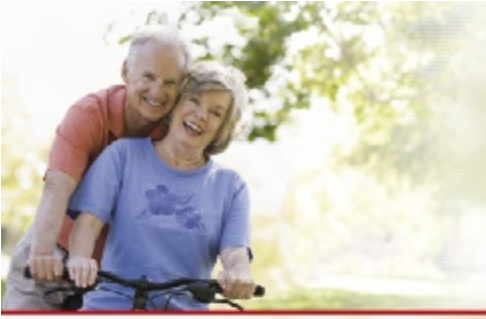
↓

- We got the support of Deputy Prime Minister and after that we begun to get some answers. We continued our fight in new media.

↓

- We are still fighting! And publishing all the information we get on our website!

ASSOCIATION CML OF SERBIA



How did we fight?

- **For patients**: we published a booklet CML Tracker in which they can write all the results from their tests and side effects they are facing.

- The goal is to make patients themselves monitor their Anzovip treatment more carefully and inform their doctors about everything.

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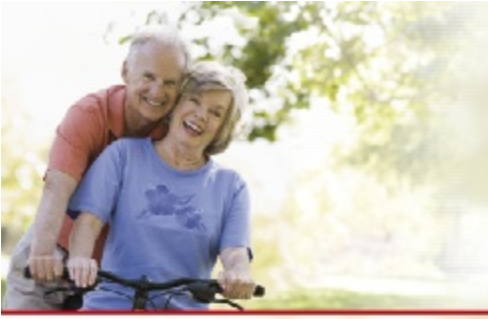


Anzovip – first results!

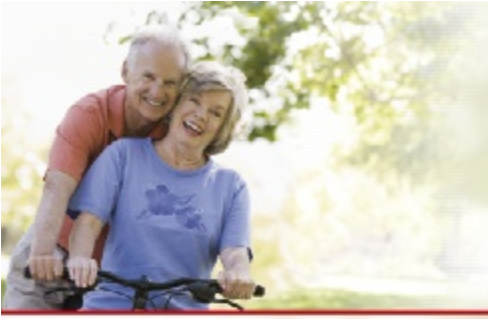
``Results of the usage of generic imatinib (Anzovip by Zdravlje Actavis)``

by doc dr Andrija Bogdanovic, president of the SHGML

- During August and September 2012 all patients were switched from Glivec to Anzovip.
- These are results of using Anzovip after 3 months.

- Two groups of patients were monitored:

1.	2.
220 CML patients on Glivec → Anzovip	**35 newly diagnosed CML patients**



Anzovip – first results!

1. **Patients using original imatinib (Glivec, Novartis) for many years and then switched to generic drug Anzovip**

- 220 patients were monitored

- 7 had lost complete hematological response they already had, but without signs of biological illness transformation → they were switched to 2nd line therapy nilotinib

- Possible reasons: patients did not used Glivec for a few weeks in July and August because of delivery problems and therapy change from Glivec to Anzovip

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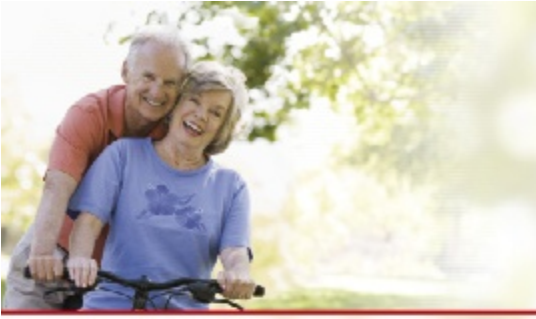

Anzovip – first results!

2. **Newly diagnosed patients and patients using Glivec less than 1 month who started with Anzovip**

- 35 patients were monitored
- All 35 patients had complete hematological response during first 2 months of using Anzovip

ANZOVIP EFFICIENCY	After 3 months	After 6 months
Number of patients	10	10
Major cytogenetic response	70 %	60 %
Complete cytogenetic response	30 %	30 %

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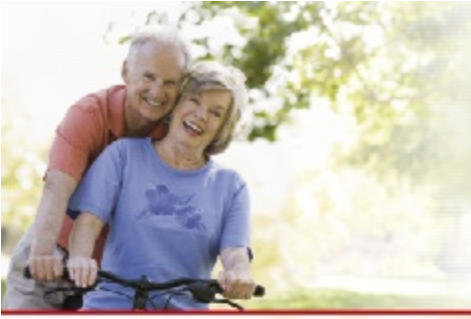

Anzovip – first results!

- **Conclusion**: CML therapy is long-lasting and definitive conclusions about the real effectiveness of generic drug Anzovip can not be concluded after 3 months and by monitoring only 10 patients.

- More accurate results can be seen after at least 6 months on all 35 patients.

- But, at the moment there is no signs of disease progress, all patients have complete hematological response, there is no unexpected toxic effects and first results of cytogenetic response are not worse than expected.

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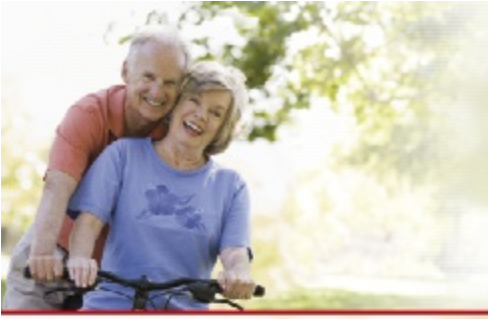


What we did and what would we do differently?

- It is important to determine the realistic goals of the fight and make benefits from it!

- Our goals at the beginning:

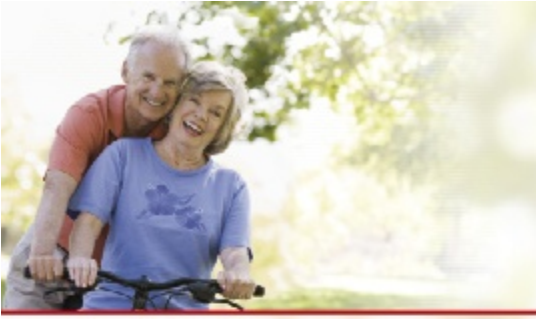
X Fighting against the generic drug – to remove Anzovip from the usage and to bring back Glivec.

✓ Increase number of patients who can get nilotinib (Tasigna) – easier transfer from imatinib to nilotinib.

✓ Make nilotinib available as 1st line therapy.

X Sending generic drug to independent testing in some laboratory in Europe by government officials – comparison testing of Anzovip & Glivec.

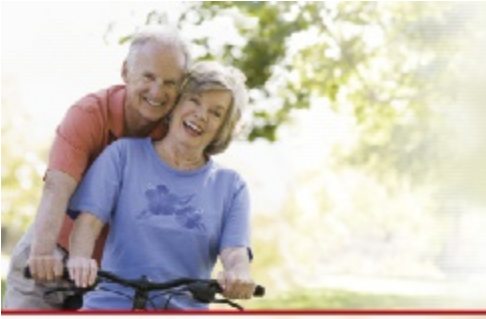
✓ Arranging with hematologists to monitor patients more carefully and to have PCRs more often.



What we did and what would we do differently?

- Our goal may have also been:
- *Fight for the patients` right not to have his/her therapy changed!*
  Meaning: patients using innovative therapy (e.g. Glivec, Tasigna) and having a good reaction to it can not have the therapy changed with the generic drug.

- Always fight for new therapies!



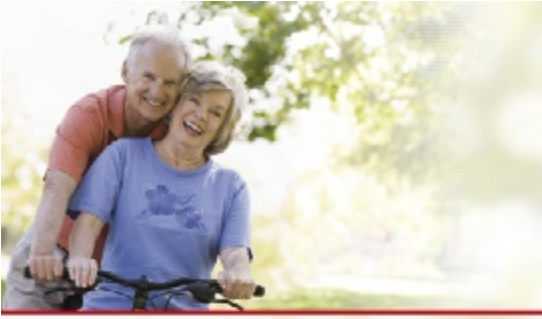
Conclusio(s)!

- We (patients and patients` groups) should not fight against generic drugs, because it is or it will be a reality, but we should fight for GOOD GENERIC DRUGS PRODUCED BY REALIBLE PHARMACEUTICALS!

- We should be informed about them: where they are produced, how, are studies of bioequivalence done or not,….

- We should pay a lot of attention to rumors – be informed about the process of generic drug registration! This is the time when we can do a lot, after registration less can be done! Start the fight before the registration!

ASSOCIATION CML OF SERBIA



QUESTIONS?

&

THANK YOU!

contact:
CML Association of Serbia
cml@cml.rs