Clinic of hemathology
Clinical centre of Vojvodina

Faculty of Medicine
University of Novi Sad,
Serbia

Clinical perspectives on CML generics- example Serbia

Ivana Urosevic

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Approval of Generic Imatinib

European Medical Agency

* Imatinib Teva 8/1/2013
* Imatinib Actavis 17/4/2013
* Imatinib Accord 1/7/2013
* Imatinib Medac 25/9/2013

Health Canada

* APO-Imatinib 19/4/2013
* Teva Imatinib 22/5/2013

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Generic Imatinib

The potential impact of different crystal forms of Imatinib used in Gleevec (beta) vs. Generic Imatinib (alpha)

Bioequivalence in children

Different absorption due to gastrectomy and change in gastric acidity in patients with GIST

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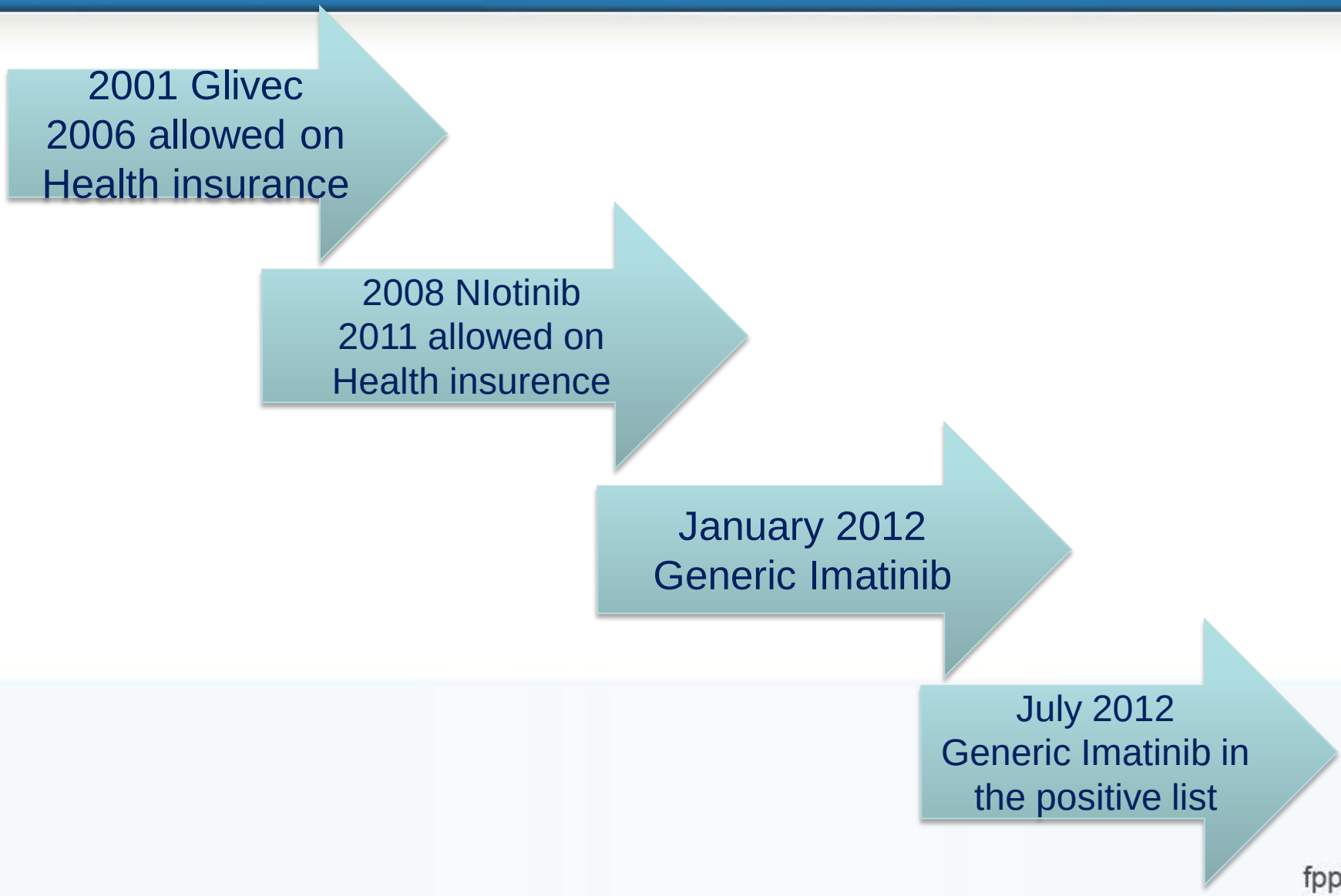
What is the situation like in Serbia?



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What is the situation like in Serbia?

- The TKI drugs on the active list in NHIF until may 2017:

  - Imatinib (Glivec®, Anzovip®, Imatinib Pharma Swiss®, Alvotinib®, Meaxin®, Plivatinib®) as a 1st line therapy

  - Nilotinib (Tasigna®) as a 2nd line therapy

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What we know about generic Imatinib in 2012?

- Four case reports of inadequate response or loss of response after switch to generic Imatinib have been published (Asfour 2009, Goubran, 2009, Chouffal, 2010, Mattar, 2010).
- Contradictory results with the generic product were reported in several observational studies, reporting the clinical outcomes based on loss of response or disease progression.

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Experiences of our centre - Clinic of hemathology, Clinical centre Vojvodina

- During August and September 2012 all patients were switched from Glivec to Anzovip and all newly diagnosed patients started with Anzovip therapy.
- These are the results of using Anzovip after 48 months.
- Two groups of patients were monitored:
- **55 CML patients on Glivec → Anzovip**
- **57 newly diagnosed CML patients**

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Results

- 55 patients treated with branded Imatinib were switched to generic Imatinib

- 14 patients **(25,45%)** had lost complete cytogenetics response they already had, but without signs of biological illness transformation → they were switched to 2nd line therapy nilotinib

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Results- de novo CML patients

- 57 newly diagnosed pts from septembar 2012 to may 2017
- Median follow up 15 months (6-57 months)
- Median age 27 (19-60)
- Median duration of Imatinib generic 15 months (6-57 months)
- 15 patients **(26,3%)** were switched to 2nd line therapy nilotinib

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Patients characteristics

Parameters	Mediana	Min	Max
Gender (M/F) 12/18			
Age (years)	49	21	77
WBC (10^9/l)	107	12	411
Hgb (g/l)	112	64	139
Platelets (10^9/l)	429,5	131	3795
Blasts %	2,5	1	8
Promyelocyte %	4	2	9
Eo %	3	1	6
Basophils %	2	1	8
Sokal score Low 23,1% Intermediate 30,7% High 46,2%			
EUTOS Low 61,5% High 38,5%			

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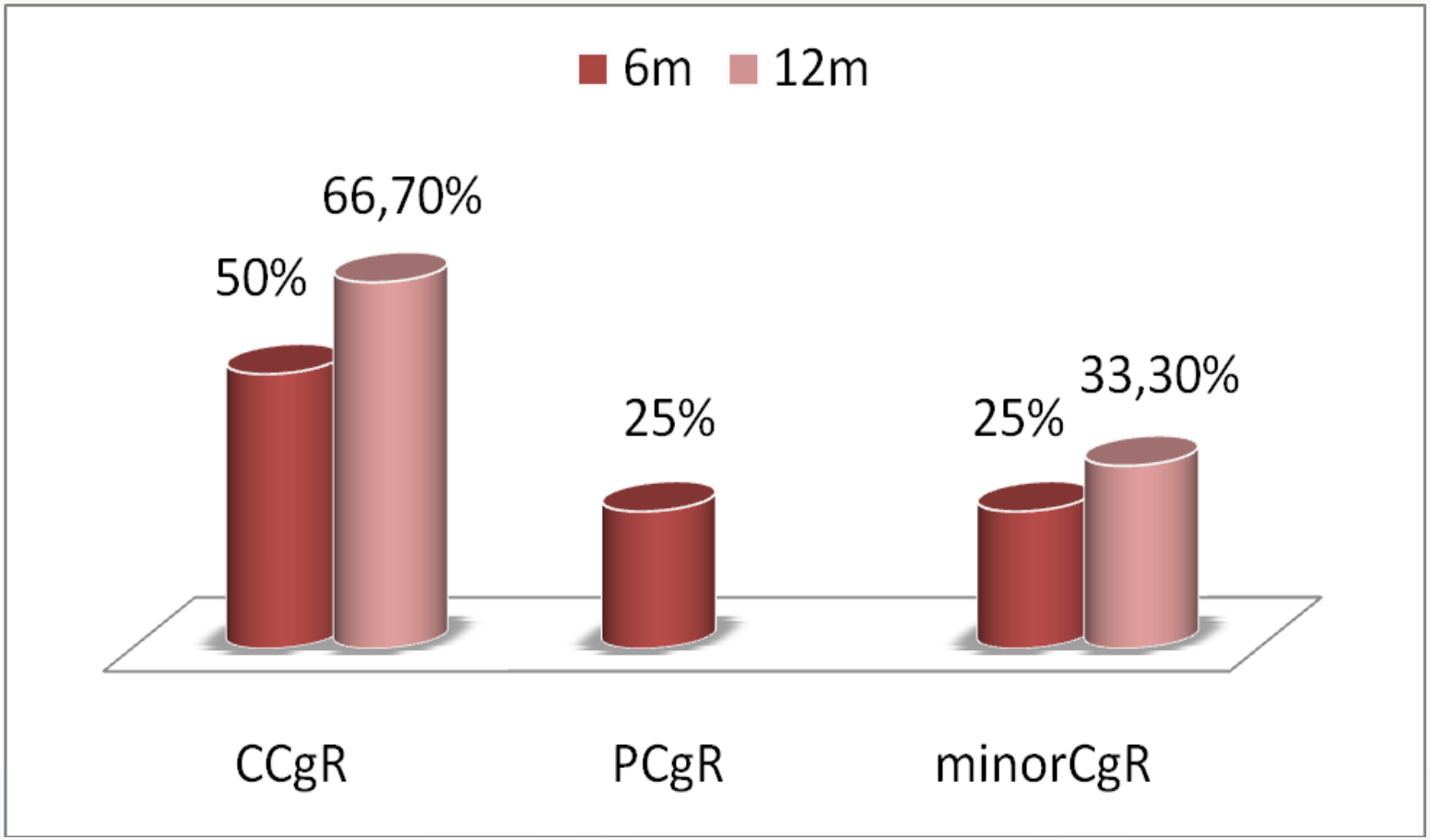
Results- cytogenetic response



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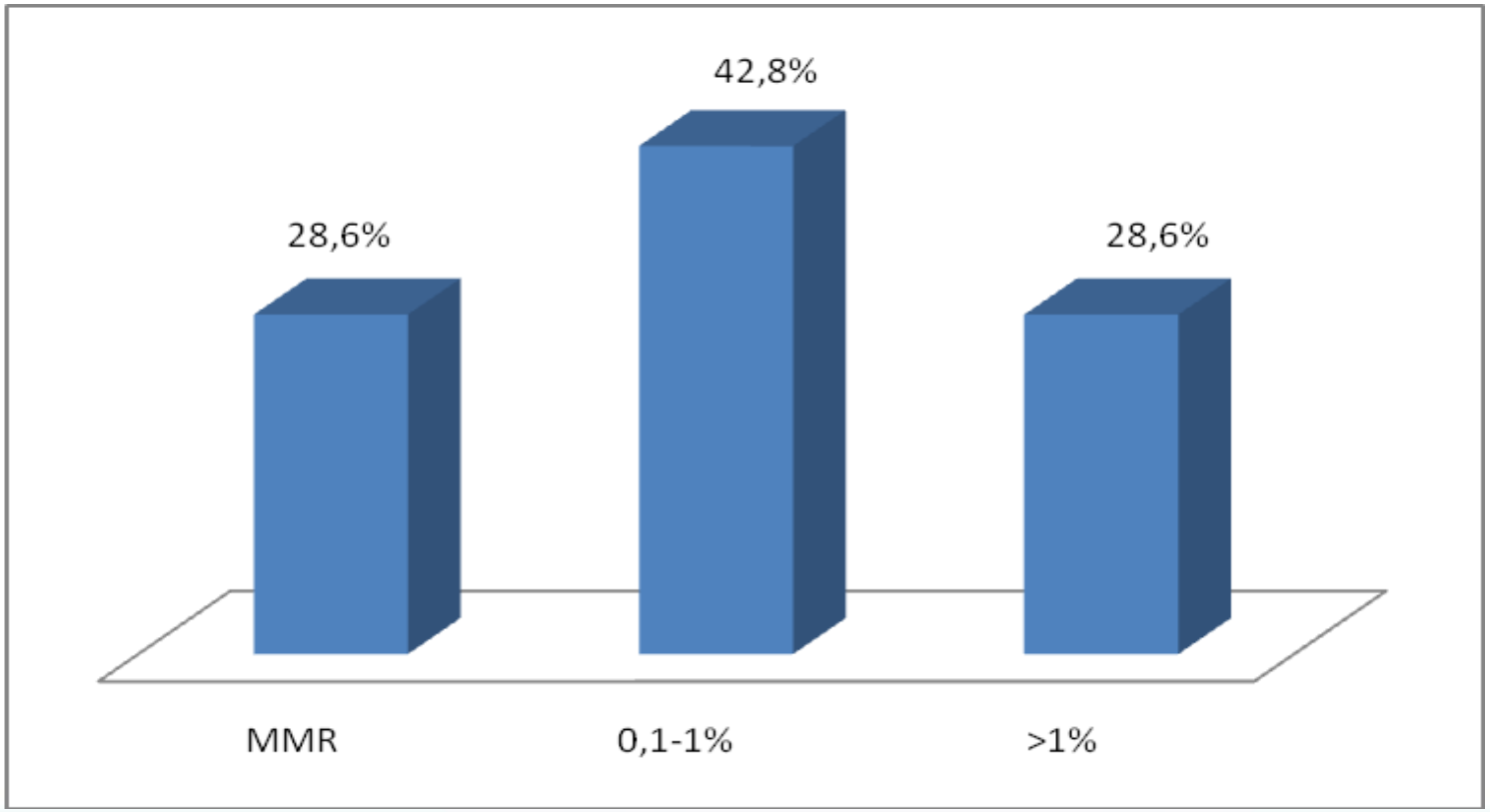
Results- molecular responce at 12 months



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Instead of conclusion

- CML patients should not be switched beetween different products for non-medical reason
- It is unknown whether patients, who responded to branded Imatinib and than switched to its copy versions, will tolerate the copy drug and maintain the previous response
- Careful follow up of a selected patients several months after the switch to generic imatinib
- Despite of the small number of patients our results in term of hematologic and cytogenetic response were close to the international series.

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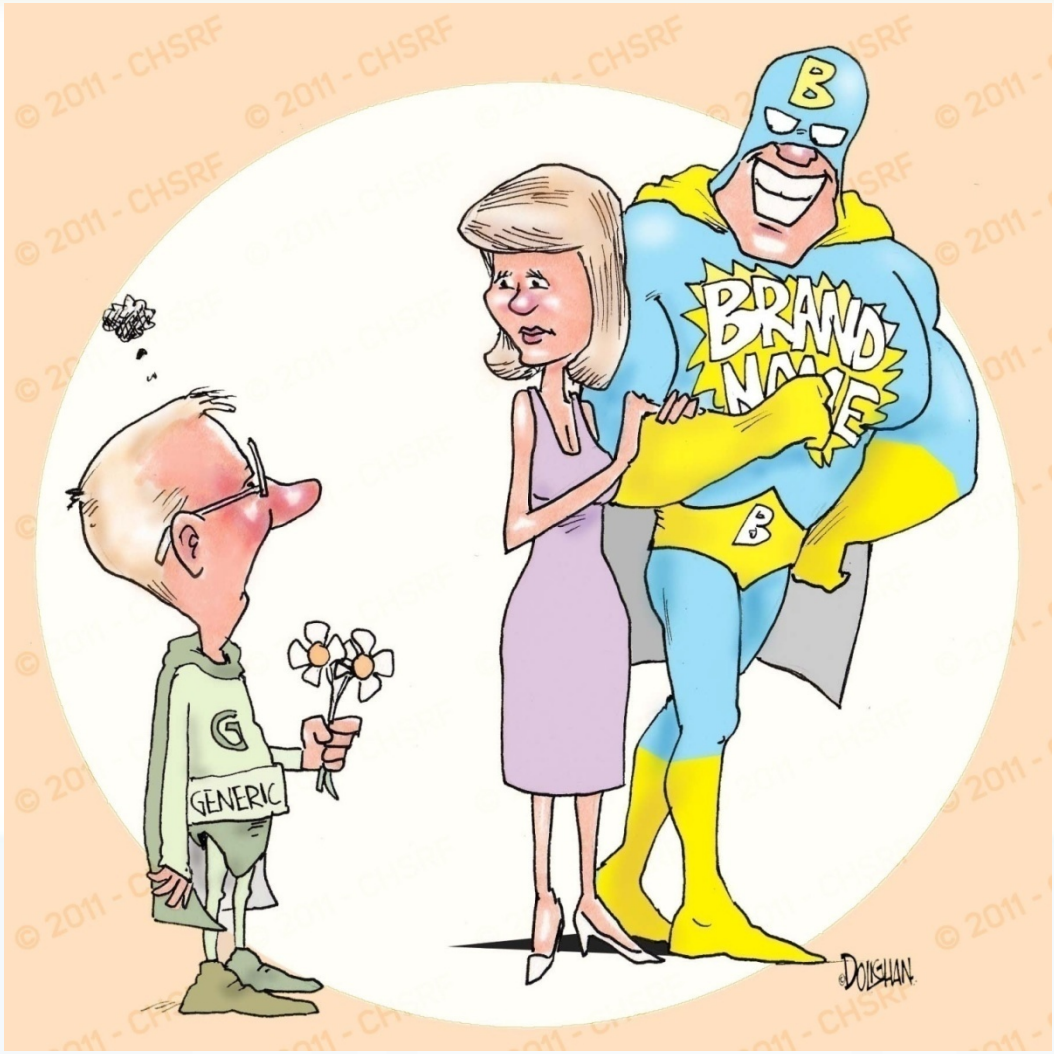
Thank You for Your attention!



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Welcome to Novi Sad!

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