



Originals, generics, copies: Results of the CML Advocates Network Survey

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Originals, copies, generics: Status quo

“Originals”

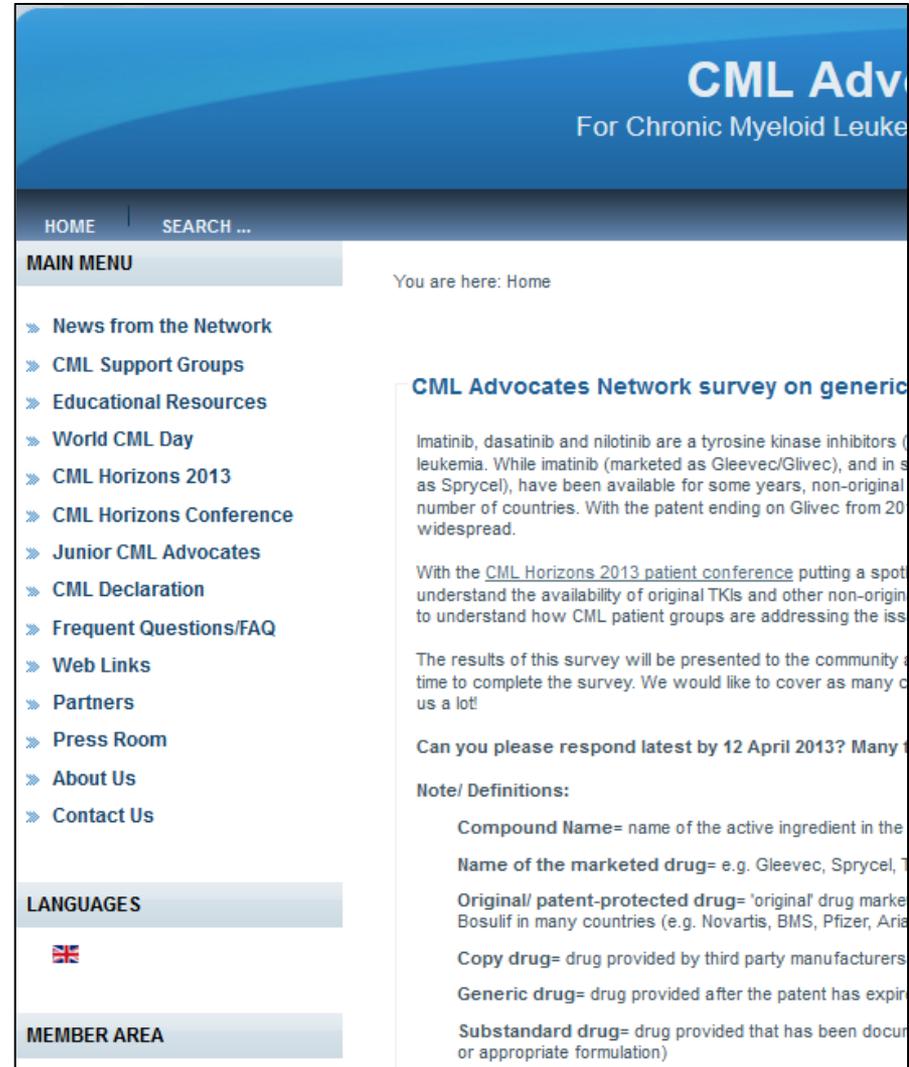
- Patented drugs Glivec (Imatinib), Tasigna (Nilotinib) and Sprycel (Dasatinib) marketed for some years.
- Imatinib patent expires in most countries by 2016, in 10 EU countries and Canada already in 2013, EMA approval for generic Imatinib pending
- Bosulif (Bosutinib) and Iclusig (Ponatinib) are newcomers.

“Generics”

- Imatinib copies available in India for some years
- Dasatinib copies available in some markets, Indian government now issued “compulsory license”

To get away from piecemeal information, CML Advocates started a global survey

- Goal: collect available information, learn from experience
- Distributed via iCMLf and CML Advocates Network
- 86 responses collected from 55 countries within 4 weeks
- Thank you for your contribution!



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CML Advocates Network survey on generic

Imatinib, dasatinib and nilotinib are a tyrosine kinase inhibitors (leukemia. While imatinib (marketed as Gleevec/Glivec), and in s as Sprycel), have been available for some years, non-original number of countries. With the patent ending on Glivec from 20 widespread.

With the [CML Horizons 2013 patient conference](#) putting a spot understand the availability of original TKIs and other non-origi to understand how CML patient groups are addressing the iss

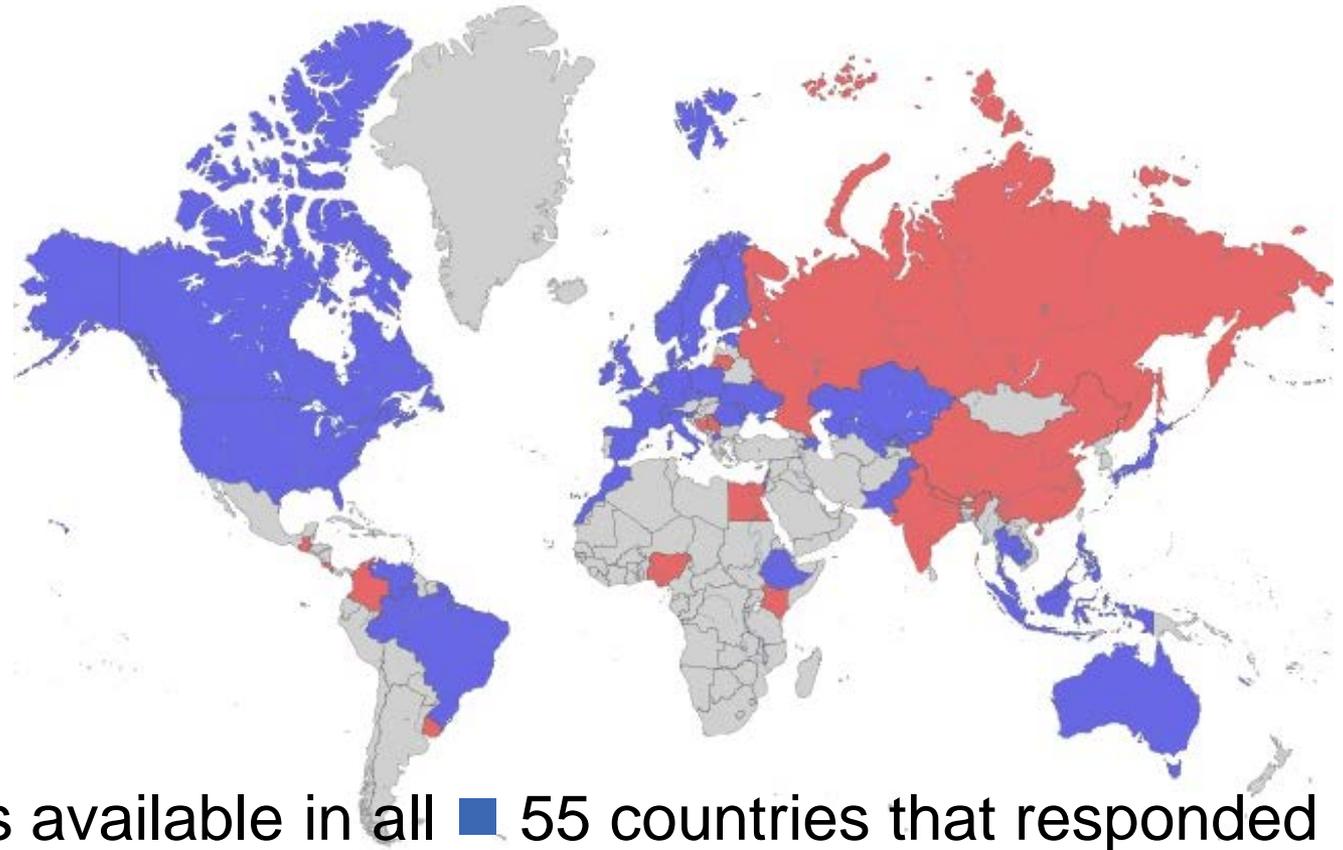
The results of this survey will be presented to the community a time to complete the survey. We would like to cover as many c us a lot!

Can you please respond latest by 12 April 2013? Many t

Note/ Definitions:

- Compound Name= name of the active ingredient in the
- Name of the marketed drug= e.g. Gleevec, Sprycel, T
- Original/ patent-protected drug= 'original' drug marke Bosulif in many countries (e.g. Novartis, BMS, Pfizer, Ari
- Copy drug= drug provided by third party manufacturers
- Generic drug= drug provided after the patent has expir
- Substandard drug= drug provided that has been docum or appropriate formulation)

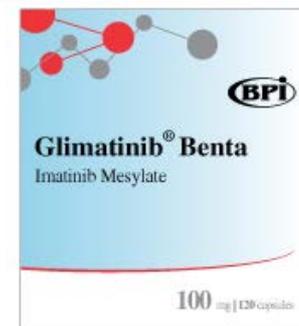
Results



- Original TKIs available in all ■ 55 countries that responded (55 Imatinib, 44 Nilotinib, 30 Dasatinib, 6 Bosutinib, 4 Ponatinib)
- Originals + copies available in ■ 14 countries with Imatinib and 3 with Imatinib+Dasatinib
- Introduced 8 years ago (India) but many in last 12 months (Costa Rica, Kenya, Lebanon, Nigeria, Serbia, Russia)

Countries where CML generics are, or have been, available

- India (about a dozen different generics)
- Bosnia & Herzegovina (Plivatiniб)
- China & Hong Kong (Veenat)
- Colombia (Leutinib, Matib)
- Costa Rica (Veenat, Imatib, Liteda)
- Egypt (Imatib)
- Guatemala (Imatib, Liteda)
- Lebanon (Glimatinib)
- Lithuania (Glipox, Imatinib Teva, Yleris)
- Nepal (Imicap)
- Nigeria (Celonib)
- Russia (Genfatinib, Philachromin-FS)
- Serbia (Anzovip)





Q3. Has any certificate of quality/ bioequivalence/ effectiveness been provided?

- On generic versions, all respondents stated that no documentation is made available
- except one hematologist from India: „Documentation required by the licensing authorities”

Non-availability of original TKI is a driver for availability of generic TKIs

India

- Original TKIs “not within the reach of the common Indian”. Hence, doctors encourage and promote generics.

Costa Rica:

- „Generic Imatinib has been registered for some time now, not a single pill has been sold yet.
- Sprycel manufacturer BMS has no presence in some 10 Central American countries and Caribbean Islands
→ Liteda (generic Dasatinib) is available.

Kenya

- Generic Imatinib from India disappeared with the rollout of the GIPAP program due to lack of market.

But times can change quickly!

- **Macedonia:** Generics are registered in authority in Macedonia, but they are not in use in this moment. Glivec will be available until May. After that Clinic of Hematology will ask for new procurement of Imatinib. I expect that advantage will be given to cheaper drugs.
- **Lithuania:** On 13 May 2013, EMA-approved generic imatinib will be reimbursed for GIST, paediatric CML patients and minor indications. Approval for adult CML patients may follow.

Q7. Observations on efficacy or unusual side effects of generic/copy TKI drugs?

- **Liteda (DA):** Hair loss, nausea, mild diarrhea, dry skin (those symptoms were absent with Sprycel)
- **Imatib (IM):** More hepatic and skin side effects / less effective. Weak efficiency, high toxicity
- **Anzovip (IM):** No unusual side effects in cohort of 30 patients, efficacy in 10 pts at 3m, and 10 pts at 6m similar to IRIS. However, in Sept-Dec 2012 loss of CCgR in 6 patients after switch to generic, but also problems with regular drug supply.
- **Leutinib, Matib (IM):** Hematologists prefer safe drugs, but must accept that patients receive copies. Some patients had adverse effects or lost response. Other patients are being treated with copies without any difference.



Q8. Has your patient organization or institution taken any action on generics, copies or substandard drugs in CML?

- **Guatemala:** We demand in the Human Rights Office as we do not have any certificate of quality, "bioequivalence" or proof of effectiveness of Cipla. In Guatemala the Social Security bought this medicine but they return to buy Glivec; only the new patients used the generic, because the Human Rights Office failed in favor of the patients that had Glivec.
- ASOPALEU appealed to Health Minister because if the generic is available in the country, the GIPAP Program will be closed. Patients with GIPAP do not have access to another drug. The Social Security have access to Glivec, Tasigna, Liteda

Actions of the community

- **Kazakhstan:** Patient association carried out huge work on clarification of bioequivalence of a preparation Immutin and its clinical researches, but results false. Lobbying of local producer of Immutin (Imatib) to Ministers of Health
- **Lebanon:** We tried to stop distributing Glimatinib. National health authority in Lebanon respond to our request and stopped distributing this unknown copy - now they give the choice to the doctors and the patients to decide what to take. Most patients choose the original drugs.
- **Russia:** Patient organization Sodeystvie has Authorized Public Expert in carrying out the monitoring of generic drugs efficiency.

Actions of the community

- **Ukraine:** OSANNA appealed to the Ministry of Health with a request to check the quality of the copies of TKI generics hit the market of Ukraine.
- **Venezuela:** We have been working with the IVSS in Venezuela, telling them not to buy generic or copies it is don't have evidence on quality and trial first in our country

We patient organisations need to watch this space!

- **Philippines:** “There are times that copies are being sold at eBay though its hard to pinpoint from what country is the origin.”
- **USA:** "Multiple websites offer "generic" versions of CML drugs to patients in the US which appear to be fraudulent offerings.
- **Guatemala:** “We need more information about the generic, copy or substandard TKI, because we are sure, that the information gives us power for our defense, our rights, our health, our opportunity to live with quality of life.”



**Results will be posted soon on
cmladvocates.net.**

Questions about the survey?

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