The Chronic Myelogenous Leukemia Society of Canada
Originators of CML AWARENESS DAY© – September 22 (9/22)
La Société de la Leucémie Myéloïde Chronique de Canada
L'origine de "CML AWARENESS DAY©" – le 22 septembre (9/22)

Generics – A Patient's Perspective

Patients as Engaged Stakeholders and Informed Decision Makers

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Background
The Savings' 'lure' for Generics

Healthcare dollars are being tightly scrutinized

Governments want to reduce spending

Private payers want to reduce spending

Generic prices in Canada are capped to 18 – 26% of branded drug prices

But it isn't just about the money!

WE NEED TO REMEMBER THE ETHICAL CONSIDERATIONS OF HEALTHCARE

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Ethical Considerations

- The right to autonomy
  - Right to all information related to disease and treatment options, including understanding of milestones and methods to achieve these
  - Assurance that patient interests come first
  - Right to individualised treatment
  - Right to refuse treatment
- Consider cost implications of generic as well as the potential to be part of a stopping trial in the future, but never make cost the impetus to do so

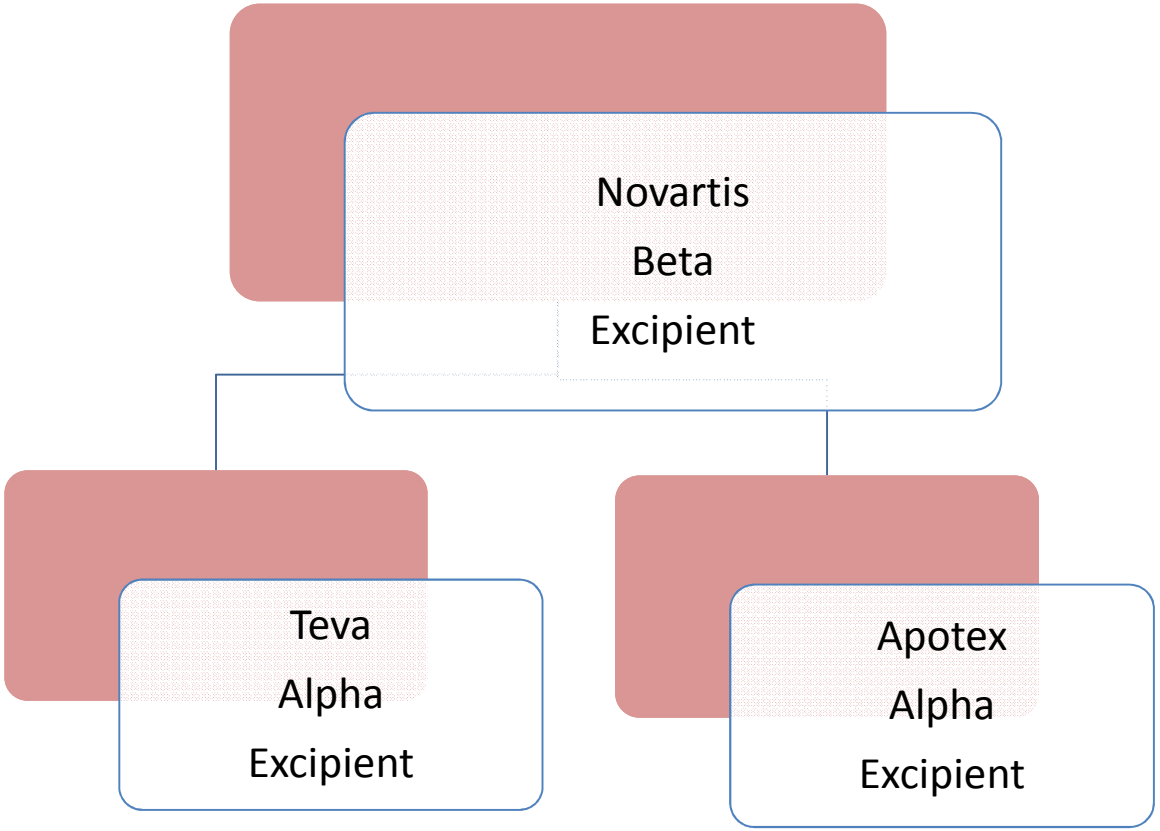
ACCEPT THE INEVITABILITY OF GENERICS

EMBRACE THE OPPORTUNITY TO ENGAGE ALL STAKEHOLDERS

First Step

Know the Drug Differences

TKI Drug Differences



‘Bio-equivalence’

- If two drugs are bioequivalent, there is no clinically significant difference in their bioavailability
- Canada bio-equivalence standards are among the highest in the world
- New Acronyms: AUC = Area Under the curve, C_{max}= Maximum Plasma drug Concentration
- Compares brand drug to generic drug plasma concentrations
- Based on confidence ratios (80 – 125%) not absolute values

‘Bio-equivalence’

- Bio-equivalence studies serve as surrogate markers
- Bio-equivalence studies for Canada were done at McGill for both the Teva and Apotex products

Second Step

Take the Opportunity to Lobby for a Change to TKI Drug Classification

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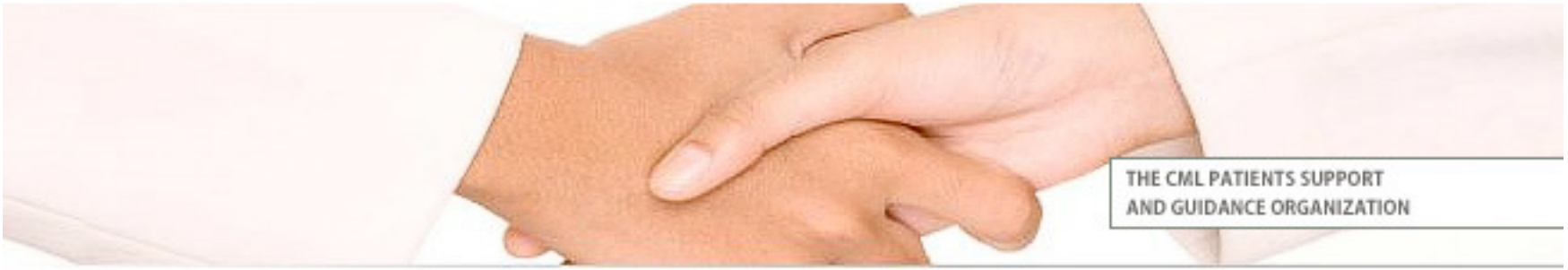
Critical Dose Drugs

- A classification reserved for drugs that may be very toxic, or may have a more narrow therapeutic range
- Based on adherence studies, especially Marin et al… ‘Missing just 3 doses of Gleevec per month greatly diminishes one’s chance to achieve an optimal response’
- Confidence interval ratios are tighter and comparative trials in patients may be warranted



Third Step

Engage All Stakeholders

Decision Makers

- Identify the stakeholders key to decision making
  - In Canada this has been Health Canada, provincial health ministers and drug executives
- Provide them with information highlighting:
  - Treatment goals and objectives (according to ELN and NCCN guidelines)
  - Importance of achieving optimal responses to drug
  - Critical Dose Drug argument – adherence data
  - Impact of Treatment Free Remission

Be a Responsible Healthcare Consumer

If your pharmacist switches you to one of the generics or advises a switch, be willing to try the generic imatinib mesylate

BUT

Minimize Your Exposure to Risk

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Be a Responsible Healthcare Consumer/Engaged CML Patient

- Make sure you ALWAYS know your latest PCR result. Record it in your diary, on your calendar, in your PCR Tracker APP or wherever you keep your CML medical information (this applies to all patients taking a TKI even if it is not a generic).

- Are you and your doctor both satisfied with your level of response on your current treatment?

- Know which generic product you have been given, that is, either Apotex imatinib mesylate or TEVA imatinib mesylate. Write it down, take a picture of the product - whatever works for you to remember it.

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Be a Responsible Healthcare Consumer/Engaged CML Patient

- Ensure that each time you renew your prescription you receive the SAME generic from the SAME manufacturer. Be ready to show the picture to your pharmacist if necessary.

- Record the date that you start taking the generic imatinib mesylate.

Be a Responsible Healthcare Consumer/Engaged CML Patient

- Carefully track and record how your quality of life has changed (if at all). Remember, as with the branded imatinib mesylate (Gleevec®, Novartis), you should report any serious side effects immediately to your Hematologist/Oncologist.

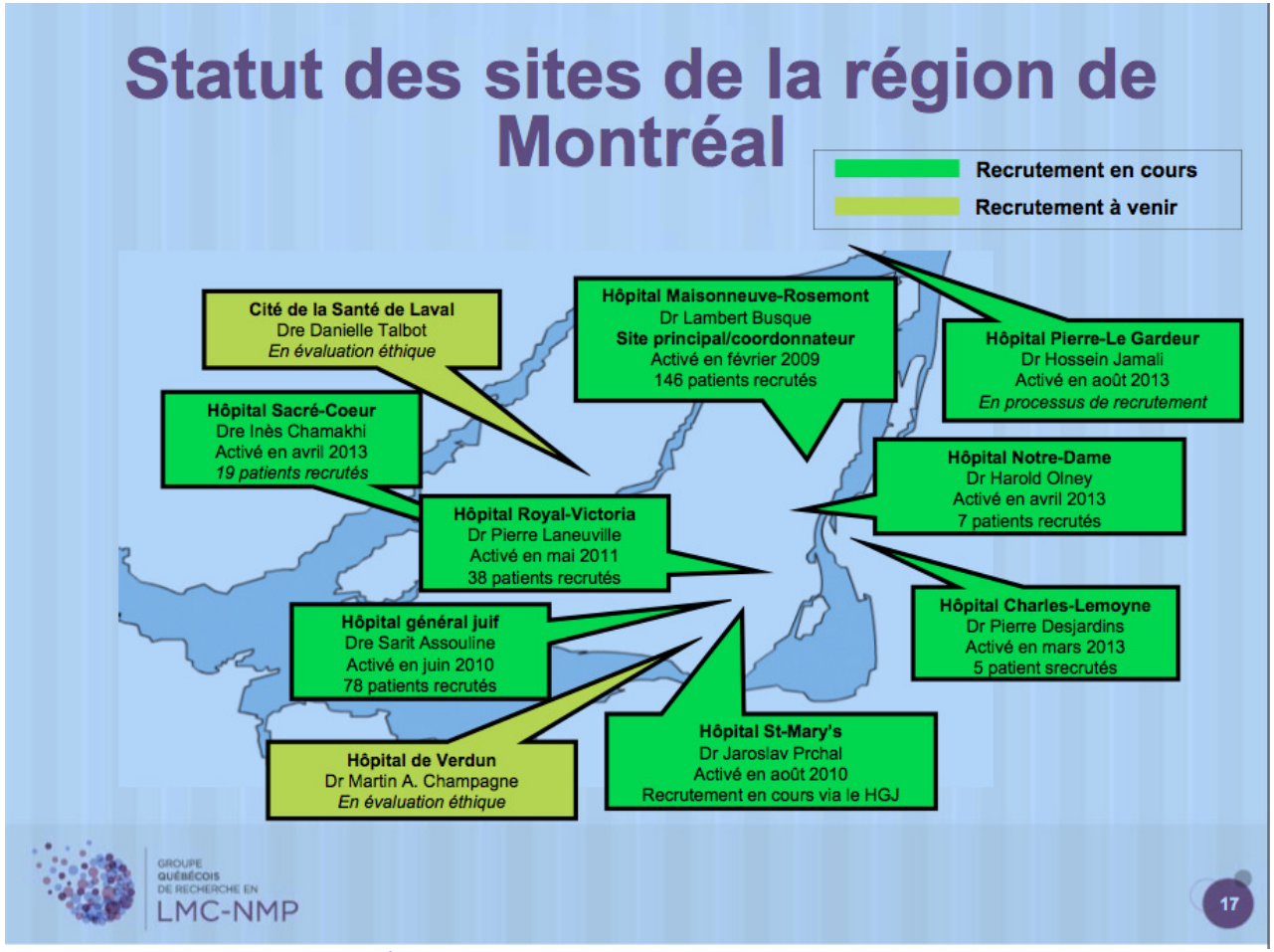
- Make sure you speak to your Hematologist/Oncologist to tell him/her that you have been or are switching to the generic imatinib mesylate and to schedule your next PCR test.

- **Be willing to share your experience with generic imatinib mesylate**
  - The CML Society of Canada has launched a survey located on our website to address experiences

An Autonomous and Engaged Patient

- Your CML journey is unique, what works for other patients may not work for you.
- Your experience with any drug, including generics, may be and often times is different from another patients.
- Do not let anyone tell you how you will or do feel, there is no conclusive data.
- Keep in mind that the Mahon data from all stopping trials to date show that patients followed closely off treatment who had a recurrence all regained their optimal response levels when placed back on the drug.

We are the Data!



CML Society of Canada Ongoing Activities

- Continue to engage Health Canada on the issue of Critical Dose Drug classification for generic imatinib
- Report our survey findings to the public if we receive a significant number of responses
- Continue to monitor adverse effects reported to Health Canada
- Continue to raise awareness of Treatment Free Remission as the new goal of treatment for CML

Lead by Being an Example of an Autonomous, Informed, Engaged Patient

THANK YOU

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