

Generic Substitution: Taking a Narrow View?

<https://marketpublishers.com/r/G9CEF394680EN.html>

Date: November 2010

Pages: 54

Price: US\$ 395.00 (Single User License)

ID: G9CEF394680EN

Abstracts

As health care expenditures rise, governments, payers, healthcare providers and patients alike are focused intently on one thing: capping runaway costs.

For the generics industry, it heralds a boom-time. In regulated markets, relatively inexpensive generic drugs are increasingly favoured by payers for their low cost and effectiveness. Prescribed by physicians but dispensed by pharmacists, drugs are increasingly substituted for cheaper generics somewhere between the doctor's surgery and home.

Yet there is an exception, and as observational evidence mounts, it's one that is worth noticing.

Narrow therapeutic index (NTI) drugs, for which small changes in concentration can lead to big alterations in efficacy and negative side effects, are the focus of much scrutiny, both by legislators and the public. As evidence in academic literature grows to indicate that formulation changes are linked to negative effects in patients, NTI substitution is becoming a hot-button topic for the generics industry.

FirstWord Dossiers tackles it head-on in our latest report, *Generic Substitution: Taking a Narrow View?* Based on expert views from leading thinkers such as University of Colorado immunosuppressant specialist Dr Uwe Christians, the report nimbly examines how some markets are implementing broad exclusion policies, while some American legislators are drafting 'carve-out' exceptions. Containing analysis, definitions, charts and interviews, the report includes an overview of immunosuppressant, antiepileptic, cardiovascular and mood-modifying drugs and the impact of substitution. Insightful, intelligent and timely, the report is critical reading for the generics industry.

The report includes:

Generic Substitution: Taking a Narrow View?

FirstWord's ExpertViews interviews with leading thinkers in the field

A concise overview of generics uptake in major markets and how NTI generic substitution differ

Key features

Analysis of how physicians, pharmacists and patients influence generic uptake

Insights into how bioequivalence is the key to the NTI substitution debate

Explanations of generic carve-outs in the US, illustrated with charts and diagrams

Analysis of the pros and cons of generics substitution restrictions in dealing with NTIs

A review of NTI drug classes, including immunosuppressant, antiepileptic, cardiovascular and mood-modifying drugs

Complete regulatory overview covering the Federal Drug Administration's position

Key quotes from the report

"The generic has to be just as good as the originator's drug. So by definition, the pharmacology of a [generic] NTI drug has to match the originator to be efficacious and not to go through cycles of toxicity. This means that NTI drugs set a pretty high bar for the generic to meet." University of Colorado immunosuppressant expert, Dr Uwe Christians.

"There is a theoretical risk about switching between NTI drugs from two generics manufacturers, where one's product is on the left side of the bioequivalence range and the other is on the right side, leading to a very large difference between them. However,

I have not seen rigorous evidence that this risk has led to bad patient outcomes in the market.” Harvard Medical School pharmacoeconomist, Dr Aaron Kesselheim.

Contents

EXECUTIVE SUMMARY

PROMOTING GENERICS UPTAKE IN THE SEVEN MAJOR MARKETS

Generic drugs use in the seven major markets

The physician-pharmacist-patient triumvirate determines the extent of generics uptake

Physicians have historically been the most important stakeholder group

Pharmacists require financial incentives to promote generics dispensing

Pharmacist substitution ruled out in the UK

The US as a mixed bag when it comes to pharmacist substitution

Patients that are cost-sensitive have the most reason to use generics

NARROW THERAPEUTIC INDEX DRUGS REPRESENT A VERY DIFFERENT PROPOSITION

Bioequivalence is key to the NTI generic substitution debate

Bioequivalence defined

Rationale for the pharmacokinetic approach

How bioequivalence criteria differ across the seven major markets

Generic carve-outs in the US

Key players in the generics carve-out debate – the usual suspects

Carve-outs as a life-cycle management strategy for the branded industry?

Generic substitution represent a major cost-saving measure for payers

Patient groups and medical associations important proponents of carve-outs

The pros and cons of generic substitution restrictions

The bioequivalence test

A small number of healthy volunteers versus a large patient population

The use of sub-therapeutic drug doses

Reduced variability of NTI drugs

Potentially large differences in bioavailability

Regulatory requirements for generic drugs on par with brands

Observational studies rather than randomized controlled trials highlight risks of generic substitution

Publication bias potentially associated with observational studies

Observational studies and confounding variables

Generic formulation changing should be no riskier than switching to a same brand formulation

Inadvertent or uninformed switching by the pharmacist
Patient compliance could be compromised

NARROW THERAPEUTIC INDEX DRUG CLASSES

Antiepileptic drugs – the link between formulation switching and breakthrough seizures

- Patients and physicians are reluctant to switch

- Concern regarding generic substitution on online forums

- The evidence for and against

Immunosuppressant drugs – disturbing the delicate balance

- Patient dosing is a closely monitored and gradual process

- Switching between immunosuppressant brands and formulations is discouraged

The complex treatment regime of transplant patients is a resistor to automatic generic substitution

- The evidence for and against

Some cardiovascular and mood-modifying have a narrow therapeutic index

- Warfarin as the most prominent narrow therapeutic index cardiovascular drug

- A number of mood-modifiers have a narrow therapeutic index

- Generic Wellbutrin cleared by the FDA

OVERVIEW

INDEX

I would like to order

Product name: Generic Substitution: Taking a Narrow View?

Product link: <https://marketpublishers.com/r/G9CEF394680EN.html>

Price: US\$ 395.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/G9CEF394680EN.html>