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Generic Substitution: Taking a Narrow View?

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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:

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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,

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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.

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Contents

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NARROW THERAPEUTIC INDEX DRUG CLASSES

OVERVIEW

INDEX

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